

EXHIBIT I
FILED UNDER SEAL

In the Matter of:

FTC, et al. v. Quincy Bioscience Holding, et al.

September 29, 2021
Mindy Kurzer, Ph.D. - Confidential

Condensed Transcript with Word Index



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<p style="text-align: right;">6</p> <p>1 PROCEEDINGS</p> <p>2 - - - -</p> <p>3 STIPULATION:</p> <p>4 All counsel present stipulate</p> <p>5 that the witness shall be sworn remotely</p> <p>6 by the court reporter</p> <p>7 * * *</p> <p>8 THE VIDEOGRAPHER: Here begins</p> <p>9 disk 1 in the video deposition of Mindy</p> <p>10 Kurzer, Ph.D., taken in the matter of</p> <p>11 Federal Trade Commission and the People</p> <p>12 of the State of New York by Letitia</p> <p>13 James, Attorney General of the State of</p> <p>14 New York v. Quincy Bioscience Holding</p> <p>15 Company, et al., in the United States</p> <p>16 District Court, Southern District of</p> <p>17 New York, matter number</p> <p>18 1:17-cv-00124-LLS.</p> <p>19 Today's date is September 29th,</p> <p>20 2021. The time on the video monitor is</p> <p>21 8:32 A.M. Central. This deposition is</p> <p>22 being held remotely via Zoom video</p> <p>23 teleconference.</p> <p>24 The court reporter is Gary</p> <p>25 Schneider on behalf of For The Record,</p>	<p style="text-align: right;">8</p> <p>1 Also with me today from Kelley Drye are</p> <p>2 Geoffrey Castello, Glenn Graham, and</p> <p>3 Caitlin Hickey.</p> <p>4 MR. de LEEUW: Michael de Leeuw</p> <p>5 from Cozen O'Connor on behalf of Mark</p> <p>6 Underwood.</p> <p>7 THE VIDEOGRAPHER: Will the</p> <p>8 court reporter please swear in the</p> <p>9 witness.</p> <p>10 Whereupon --</p> <p>11 MINDY KURZER, Ph.D.,</p> <p>12 was called as a witness and, after having been</p> <p>13 first duly sworn, testified as follows:</p> <p>14 E X A M I N A T I O N</p> <p>15 BY MR. WONE:</p> <p>16 Q. Good morning, Doctor.</p> <p>17 A. Good morning.</p> <p>18 Q. How do you pronounce your last</p> <p>19 name?</p> <p>20 A. Kurzer.</p> <p>21 Q. Kurzer.</p> <p>22 A. I'm sorry, Mr. Wone. You</p> <p>23 were -- you were a little bit -- your audio wasn't</p> <p>24 following your video for a moment.</p> <p>25 Q. Okay. Can you hear me fine now?</p>

<p style="text-align: right;">9</p> <p>1 A. I can hear you fine now.</p> <p>2 Q. Great.</p> <p>3 So I'll start off this morning</p> <p>4 thanking you for joining us today. I want to go</p> <p>5 over a few procedures which hopefully will make</p> <p>6 things a little bit easier for both of us today.</p> <p>7 Okay?</p> <p>8 A. Yes.</p> <p>9 Q. Today I'll be asking you a</p> <p>10 series of questions. If you don't hear a</p> <p>11 question, please say so and I'll repeat it. If</p> <p>12 you don't understand a question, please say so and</p> <p>13 I will try to rephrase it.</p> <p>14 If you realize an answer that</p> <p>15 you gave earlier was inaccurate or incomplete,</p> <p>16 please let me know and you'll have -- you want to</p> <p>17 correct it or supplement it and -- you'll have a</p> <p>18 chance to do so.</p> <p>19 If you'd like to take a break at</p> <p>20 any point, please let me know and we can</p> <p>21 accommodate you. My only request is if a question</p> <p>22 is pending, that you answer the question before we</p> <p>23 take a break.</p> <p>24 Do you understand?</p> <p>25 A. I do, yes.</p>	<p style="text-align: right;">11</p> <p>1 consult other sources of information, so any</p> <p>2 papers, notes, cellphones, computers, tablets or</p> <p>3 any other device or document during the</p> <p>4 deposition.</p> <p>5 Do you understand?</p> <p>6 A. I do understand, yes.</p> <p>7 Q. During the deposition, when</p> <p>8 we're on the record, you cannot communicate with</p> <p>9 anyone else, including your attorneys.</p> <p>10 Do you understand?</p> <p>11 A. Yes.</p> <p>12 Q. The only exception to that is</p> <p>13 during breaks. During breaks, you're free to talk</p> <p>14 with your attorneys.</p> <p>15 During the deposition, I will be</p> <p>16 showing you documents through AgileLaw. You'll</p> <p>17 have a chance to look at them, and then I will ask</p> <p>18 you some questions. The documents will be marked,</p> <p>19 like you saw last week in the lower right-hand</p> <p>20 corner of the first page, with an exhibit number.</p> <p>21 And during the course of the deposition, we'll be</p> <p>22 referring to those exhibit numbers for what</p> <p>23 document you should be looking at at a particular</p> <p>24 moment.</p> <p>25 Do you understand the</p>
<p style="text-align: right;">10</p> <p>1 Q. If you answer a question, I'll</p> <p>2 assume you've heard it, understood it, and given</p> <p>3 me your best recollection.</p> <p>4 Because the court reporter is --</p> <p>5 because the deposition is being taken remotely,</p> <p>6 it's important that you answer all questions</p> <p>7 verbally. The court reporter cannot record hand</p> <p>8 gestures or nodding or shaking of heads.</p> <p>9 Do you understand?</p> <p>10 A. I do, yes.</p> <p>11 Q. It's also important that only</p> <p>12 one person speak at a time, so if you could please</p> <p>13 let me finish my question before you begin your</p> <p>14 answer, and I will make sure to let you finish</p> <p>15 your answer before I ask my next question.</p> <p>16 Today you should testify from</p> <p>17 your memory and from using the exhibits that were</p> <p>18 introduced.</p> <p>19 Were you able to access</p> <p>20 AgileLaw?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. So that program -- as we</p> <p>23 discussed last week in the trial run, that program</p> <p>24 will display all of the documents that you should</p> <p>25 use during today's deposition. I ask that you not</p>	<p style="text-align: right;">12</p> <p>1 instructions?</p> <p>2 A. I do understand the</p> <p>3 instructions, yes.</p> <p>4 Q. And is there --</p> <p>5 MS. METZINGER: And --</p> <p>6 MR. WONE: -- any reason --</p> <p>7 MS. METZINGER: Sorry. Go</p> <p>8 ahead.</p> <p>9 MR. WONE: No, go on.</p> <p>10 MS. METZINGER: I was just going</p> <p>11 to ask that, as we've done in prior</p> <p>12 depositions, designate the transcript,</p> <p>13 at least provisionally, as attorneys'</p> <p>14 eyes only pursuant to the protective</p> <p>15 order, and we will follow-up with more</p> <p>16 specific designations once we receive</p> <p>17 the transcript.</p> <p>18 MR. WONE: Okay.</p> <p>19 MS. METZINGER: Thank you.</p> <p>20 BY MR. WONE:</p> <p>21 Q. Dr. Kurzer, do you understand</p> <p>22 the instructions I gave you?</p> <p>23 A. I do understand the</p> <p>24 instructions, yes.</p> <p>25 Q. And can you think of any reason</p>

13

1 **why you wouldn't be able to answer my questions**
2 **today truthfully and fully?**

3 A. No, there is no reason.

4 **Q. Can you please state and spell**
5 **your name for the record.**

6 A. My name is Mindy Kurzer,
7 M-I-N-D-Y, last name K-U-R-Z-E-R.

8 **Q. Okay. I've introduced and**
9 **marked the first Exhibit as MK1.**
10 **(Marked Exhibit MK1.)**

11 BY MR. WONE:

12 **Q. You should see that on your**
13 **screen, Dr. Kurzer.**

14 A. I do.

15 **Q. Is Exhibit MK1 the expert report**
16 **that you prepared for -- on behalf of the**
17 **defendants in this case?**

18 A. Yes, it is.

19 **Q. And if you could turn to**
20 **Exhibit A of your expert report or what's been**
21 **designated as MK1, please.**

22 A. And would that be at the very
23 end or where -- where would that -- where would
24 the exhibit be?

25 **Q. It should start on approximately**

14

1 **page 50, 50 out of 65.**

2 A. Okay. Yes.

3 **Q. And what is Exhibit A,**
4 **Dr. Kurzer?**

5 A. Exhibit A is my curriculum
6 vitae.

7 **Q. Where did you get your**
8 **undergraduate degree, Mr. Kurzer?**

9 A. My undergraduate degree was from
10 the State University of New York at Buffalo.

11 **Q. And what did you study at**
12 **Buffalo?**

13 A. I studied history and
14 philosophy.

15 **Q. And when did you graduate?**

16 A. I graduated in 1973.

17 **Q. And what did you do after you**
18 **graduated?**

19 A. After I graduated, I did some
20 various kinds of work, and then I started a
21 master's program at the University of California
22 at Berkeley, master's in nutrition.

23 **Q. And what was the nature of your**
24 **work between graduating Buffalo and starting your**
25 **master's program?**

15

1 A. I was a mail handler at the Post
2 Office, and that was the primary work. I also was
3 a substitute teacher in daycare centers.

4 **Q. Can you describe your graduate**
5 **program?**

6 A. My graduate program was in
7 nutritional science. I have a master's degree in
8 nutritional science from the University of
9 California Berkeley, and I also have a Ph.D. in
10 nutritional science from the University of
11 California at Berkeley. And nutritional science
12 is a combination of physiology and biochemistry.
13 It's a science-based degree, and I would say that
14 it is an applied science. So it's the -- and I
15 focused on human nutrition in my research. So
16 I -- for my -- both my master's and my doctorate,
17 I performed research and I published papers from
18 that research, and they were primarily human
19 clinical studies.

20 **Q. Can you describe the topics or**
21 **areas that your research focused on?**

22 A. Sure.

23 So my doctoral project was a
24 clinical study investigating the effect of a
25 low-calorie diet on reproductive hormones in young

16

1 women.

2 **Q. Did you conduct that study**
3 **yourself?**

4 A. I was the -- as a student, I was
5 not the principal investigator. My major advisor
6 was the principal investigator for purposes of
7 reporting and regulation, et cetera. I did -- I
8 was the person who ran the study. I recruited the
9 participants. I worked with them on the -- on a
10 daily basis on all of the aspects of the study.
11 And I also analyzed the data and wrote reports for
12 publication.

13 **Q. Was that study a randomized**
14 **controlled trial?**

15 A. It was not, no.

16 **Q. What kind of study was it?**

17 A. It was a -- it was a study in
18 which each person was their own control. So
19 rather -- a randomized control trial will have two
20 separate groups, like parallel arm study, and this
21 was -- this was not. So each person -- and it was
22 a small study. They there were only six people.
23 And the reason is because the University of
24 California at Berkeley had a metabolic unit in
25 which many of the studies that have been used to

<p style="text-align: right;">17</p> <p>1 define requirements for nutrients such as protein 2 were done on very small populations. It's a 3 live-in unit where six people -- there were six 4 beds. And metabolic -- this was a metabolic study 5 and -- in which you study a small amount of people 6 and you study them very intensively. And my study 7 was designed to be performed in that metabolic 8 unit. And, unfortunately, the metabolic unit 9 grant was not renewed, and so my study was done on 10 an outpatient basis. And -- and as a result, it 11 was -- you know, we had to shift gears and pivot 12 to do it on an outpatient basis. But it was a 13 very small number of people. It was six woman, 14 and they consumed either a regular diet, and I 15 followed them for about six weeks, or I put them 16 on a very low-calorie diet, about 40 percent of 17 their required calories, for six weeks. And I 18 measured reproductive hormones every other day 19 because I was interested in the effect on the 20 menstrual cycle, how energy deprivation and a 21 low-calorie diet affects the menstrual cycle and 22 reproductive hormones in young women. And so we 23 measured hormones every other day on these women. 24 Even though it was an outpatient study, they came 25 into the -- to the facility, to the clinical</p>	<p style="text-align: right;">19</p> <p>1 consumed on the outside for a period of about 2 two months. These participants lived in the 3 metabolic ward for two or three months and they 4 consumed a liquid diet. And in this case, in 5 this -- generally. But in this study, they 6 consumed the same diet that they had consumed on 7 the outside. And the purpose was to try to 8 validate the results of the real-life study with a 9 controlled study in a controlled environment. And 10 that was not a study that I designed. That was a 11 study that I supervised, ran, recruited 12 participants for, worked with the participants as 13 an employee. 14 Q. When you say "running clinical 15 trials," did it involve analyzing data? 16 A. For my own research, for the 17 research that was part of my master's and my Ph.D., 18 yes, it involved analyzing data. For the research 19 which I -- in which I was acting as a staff 20 member, I was not involved in analyzing the data. 21 I was involved in running the trial, basically. 22 Q. Okay. Were you involved in 23 running any other trials? 24 A. At that point, no. Those -- 25 those were the studies that I was involved and</p>
<p style="text-align: right;">18</p> <p>1 facility. 2 Q. Were you involved in the design 3 of the study? 4 A. I was, yes. 5 Q. Were you involved in any other 6 research during your master's or Ph.D. programs at 7 Berkeley? 8 A. Yes. I did some -- I 9 participated and actually ran a few clinical 10 trials because I had a gap of a couple of years 11 between my master's and my Ph.D. during which I 12 worked as a research scientist in the department 13 and I ran a couple of different clinical trials, 14 one of which was to evaluate the effect of 15 consumption of beans, legumes, on gas production. 16 And so we had a group of men who consumed a meal 17 of beans and we collected their intestinal gas and 18 measured it in order to -- and we gave them 19 different fractions, different processed parts of 20 the beans in order to determine what part -- 21 portion of the beans was responsible for producing 22 the gas. So that was one study that we did. 23 Another study was a study in 24 which we had participants in the metabolic ward 25 consuming exactly the same diet that they had</p>	<p style="text-align: right;">20</p> <p>1 highly responsible for as a student. 2 Q. Okay. Did any of your research 3 work or coursework involve cognitive function? 4 A. No, only my own. 5 Q. And what was that? Oh, only 6 your own. 7 A. Yes. 8 Q. Meaning yourself. 9 A. Yes. Sorry. 10 Q. I understand. 11 Okay. So what did you do after 12 you finished your Ph.D. at Berkeley? 13 A. After I finished my Ph.D. at 14 Berkeley, I was a postdoctoral fellow 15 in San Francisco at the University of California 16 San Francisco where I did very basic science work 17 on endocrinology. I was very interested in the 18 relationship between diet, nutrition, and 19 hormones. And so I worked with a very 20 well-known -- particularly reproductive hormones. 21 So I worked with a very well-known scientist in 22 the field of estrogen metabolism at the University 23 of California San Francisco, and I did 24 self-culture studies looking at the effects of 25 various compounds on estrogen synthesis primarily</p>

21

1 in adipose cells.

2 **Q. You used the phrase "basic**
3 **science." What did you mean?**

4 A. By this I mean I did not have
5 human subjects. This was wet lab cell culture
6 work, in vitro, in vitro work as opposed to human
7 studies.

8 **Q. Did any of your postgraduate**
9 **work involve any aspect of cognitive functions?**

10 A. No, it did not.

11 **Q. What did you do after you**
12 **finished this postgraduate work?**

13 A. After I finished that
14 postgraduate work, I actually -- I'm sorry, I'm
15 getting two things chronologically mixed up.
16 Directly after my -- my Ph.D., before I went to
17 San Francisco, I received a NATO postdoctoral
18 fellowship to work in Europe for a year to do
19 research. And so for a year, in between Berkeley
20 and San Francisco, I lived in Rome, and then I
21 lived in Denmark performing nutrition research
22 with -- with scientists there as a continuation of
23 my training. So that was my first postdoc. And
24 then the second postdoc was in San Francisco.

25 **Q. What was the -- what was the**

22

1 **focus of the first postdoc in Europe?**

2 A. I did two different things. In
3 Rome -- I was in Rome for four months and I worked
4 at the National Institute of Nutrition in Rome
5 with the director, and I helped them with some
6 epidemiological studies of children, looking at
7 reproductive hormones and diet at different ages
8 in children. And so that was kind of a little bit
9 of a training experience for me to just get to see
10 what they were doing.

11 From there, I went to Odense,
12 Denmark, to the University of Odense, and I worked
13 in a lab with Loris Garbi, who was an expert in
14 energy expenditure and energy metabolism, and I
15 spent almost a year with him working on studies
16 looking at energy expenditure and the factors that
17 influence it in young people.

18 **Q. Did any of your research in**
19 **Europe involve randomized controlled trials?**

20 A. No.

21 **Q. Did any of your research in**
22 **Europe -- while in Europe involve cognitive**
23 **function?**

24 A. No.

25 **Q. So after you finished that**

23

1 **postdoctorate work experience in Europe, then you**
2 **went to San Francisco?**

3 A. That's right, exactly. I came
4 home, and then I started at San Francisco, and I
5 was there for two and a half years.

6 **Q. Okay. And what did you do after**
7 **those two and a half years in San Francisco?**

8 A. After the two and a half years
9 in San Francisco, I took a position at the
10 University of Minnesota as an assistant professor,
11 and I've been there for over 30 years.

12 **Q. Can you describe your work at**
13 **the University of Minnesota?**

14 A. Yes. At the University of
15 Minnesota, I have a few different major
16 responsibilities. One is research program, and my
17 research program over the 30 years has focused --
18 it's shifted somewhat, but most of the 30 years
19 has focused on human clinical studies, evaluating
20 the effects of dietary substances and dietary
21 supplements on health endpoints in humans and --
22 with particular interest in cancer prevention and
23 heart health, et cetera, looking at biomarkers of
24 these -- of these disease states. So not looking
25 at the diseases themselves, but looking at markers

24

1 of them. So that's been a lot of what I've done
2 for my research.

3 I've had a pretty big research
4 program. It has been primarily funded by the
5 National Institutes of Health and other federal
6 agencies, the Department of Defense, and very -- I
7 have a little bit of corporate sponsorship of --
8 of some of my research, but very little. It's
9 mainly federal sources. So that's been my
10 research program.

11 I also teach. I teach
12 nutrition. I've taught a few different courses.
13 The main -- my main responsibility has been
14 Introductory Nutrition which I teach to freshmen
15 through senior primarily at the university. And
16 so it's an overview of nutritional science. So
17 that's my main teaching responsibility.

18 I also for the last ten or so
19 years have had a big responsibility for
20 administration. I direct an institute at the
21 University of Minnesota called the Healthy Food,
22 Healthy Lives Institute which focuses on the food
23 and health and the integration of health science
24 and agriculture because I am -- although I
25 consider myself to be in allied health science,

<p style="text-align: right;">25</p> <p>1 I'm in a college of agriculture. So we have a 2 unique opportunity to bring together agriculture 3 and food production with the -- with health and -- 4 with human health. And so that's what my 5 institute does, which I've been spending a lot of 6 time directing for the last ten years.</p> <p>7 Q. If I understood you correctly, 8 you mentioned your research program involved human 9 randomized controlled trials?</p> <p>10 A. Yes.</p> <p>11 Q. And what was your role in these 12 randomized controlled trials?</p> <p>13 A. Principal investigator. I 14 have -- I have received grants for and been the 15 principal investigator of seven or eight clinical 16 trials. I was responsible for writing the 17 protocol, in some cases working with colleagues on 18 it, in some cases having almost the entire 19 responsibility myself, in some cases leading a 20 research team. But I've been in a leadership 21 position with all of them, running the trials, 22 supervising graduate students who would be 23 interacting with participants, working with 24 statisticians closely to analyze the data, 25 writing -- writing the publications or supervising</p>	<p style="text-align: right;">27</p> <p>1 A. I was involved as a member of 2 the team. And so there would be, for example, 3 conference calls periodically to discuss the 4 trial. When the -- when the study -- in the 5 beginning when the study was being designed, when 6 the study -- when the grant was being written, I 7 was involved and consulted about the writing of 8 the grant, about the study design, about the 9 endpoints that I was focused on, which were my 10 area of expertise in relation to the study which 11 was phytoestrogens and -- in -- in most of these 12 studies and -- so that before the study, I was 13 involved as a consultant in a way on the design. 14 And I wasn't the driver, but I was part of a team. 15 And then during the study, there were regular 16 meetings to discuss how the study was going, 17 problem solve, et cetera. And then I did not take 18 primary responsibility for writing the 19 publications, but I read and edited and was 20 involved in the writing of all of the publications 21 that -- that have my name on it that came from 22 those collaborative studies.</p> <p>23 Q. When you say you were a 24 consultant in the design, did that include working 25 on the protocol for the study?</p>
<p style="text-align: right;">26</p> <p>1 my students. 2 I -- as -- because I'm an 3 educator, I -- it's very important to me that 4 graduate students have experience writing 5 publications. So even though in some cases it 6 might be easier for me to write the paper, the 7 students would write the first draft, and then I 8 would work with them on many iterations until 9 published so that I would feel that if my name's 10 on the paper, then I can stand behind anything 11 that's in it.</p> <p>12 So I would say that my role in 13 the trials that I'm talking about here has been 14 very primary.</p> <p>15 I've always done quite a bit of 16 collaborative work with -- in which other 17 researchers were the principal investigators on 18 the clinical trial and I was a collaborator or a 19 co-investigator and was involved in aspects of the 20 study but not -- I did not have primary 21 responsibility for the study.</p> <p>22 Q. And in those studies that you 23 played a collaborative role, what was your -- can 24 you describe how you were generally involved in 25 the study?</p>	<p style="text-align: right;">28</p> <p>1 A. Yes. In particular, the part of 2 the protocol that I was the most involved with.</p> <p>3 Q. And what part would that be?</p> <p>4 A. That would be the -- because -- 5 I'm thinking of one study in particular which was 6 a study of the effect of dietary soy constituents 7 called isoflavones which are phytoestrogens, plant 8 estrogens. The study was looking at the effects 9 on bone health in -- in postmenopausal women and 10 perimenopausal women in order to see if these 11 exogenous phytoestrogens might prevent bone loss 12 with aging. So I was the expert on phytoestrogens 13 in that -- on that team. I was not an expert on 14 bone. So the primary -- the principal 15 investigator was an expert on bone, and so she 16 knew how to design the study with respect to the 17 bone endpoints, but I was an expert on how the 18 supplement should be taken, how compliance should 19 be evaluated, how the measurements would be made 20 to determine what the levels were, et cetera.</p> <p>21 Q. Did any of the trials that you 22 worked on as part of your research program involve 23 any aspect of cognitive function?</p> <p>24 A. No.</p> <p>25 Q. How about any of the classes</p>

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1 **you've taught? Did any of them involve cognitive**
2 **function?**

3 A. You know, I've done a little bit
4 of work on cognitive function. I wrote a paper on
5 food and mood many years ago, which is in my list
6 of publications. I was asked -- I was asked to
7 write that paper, and so I wrote a paper on it,
8 and it was called food and mood, and this is many,
9 many years ago. And in my classes, occasionally
10 the subject of diet and cognitive function does
11 come up. Diet and mental health, et cetera, for
12 example, in my class that I teach Introductory
13 Nutrition, the issue of the effect of
14 micronutrients on mental health is something that
15 we discuss. So it is something that I have -- I
16 have had the opportunity to -- to look at, to
17 think about, to talk about, to teach about in the
18 context of nutrition as a small part of my work
19 that I've done.

20 **Q. And in writing that paper on**
21 **food and mood, did you conduct research for it?**

22 A. No, I didn't. That was a --
23 that was a literature review, so that was a review
24 of what was known at that time.

25 **Q. You also mentioned an institute**

30

1 **that focused on food and health?**

2 A. Yes.

3 **Q. Can you -- did any of -- has any**
4 **of your work for the institute involved cognitive**
5 **function?**

6 A. The work that I've done at the
7 institute has involved cognitive function
8 peripherally. So one of the things that I -- that
9 I've done as director of the institute is to work
10 with a local Native American tribe to host a
11 conference on Native American nutrition. And
12 we've held four of those conferences, and the
13 fifth one is going to be held next May. It's a
14 two-and-a-half-day conference with about 600
15 people coming from all over the country and
16 Canada, some other countries as well. And there
17 is a lot -- a great interest in the effect of food
18 on mental health for Native Americans, the effect
19 of trauma on -- on -- the effect of trauma on
20 mental health and how that's affect- -- and how
21 the loss of traditional foods has affected mental
22 health.

23 So we've talked about mental
24 health not cognitive function in the sense of
25 detailed studies of cognitive function, but in a

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1 more general sense mental health. We've had
2 speakers. We've had scientific sessions on those
3 topics which -- which I've invited the speakers to
4 and, et cetera, got to know the speakers well.

5 **Q. So you've mentioned research**
6 **program, your teaching, your institute while at**
7 **the University of Minnesota. Is there any other**
8 **work experiences in your position?**

9 A. My position is primarily
10 education, research, and then, of course, service
11 or public engagement. And so I have done a lot --
12 quite a lot of service at the University of
13 Minnesota. I've chaired many committees. I've
14 chaired search committees for dean positions, for
15 departments head positions, for faculty positions.
16 I've been on the -- I am currently on the college
17 promotion and tenure committee, which I've served
18 on twice before, where we evaluate faculty to
19 determine whether or not they deserve promotion
20 and/or tenure. So I've been highly involved in
21 that.

22 Some of my teaching -- I also
23 for ten years was director of the nutrition
24 graduate program. And in that capacity, I oversaw
25 the entire graduate program. We had about -- I

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1 believe about 50 graduate students at that time,
2 and I taught an introductory class to the graduate
3 students in which we discussed good research
4 practices, we discussed examples of fraud in
5 science and how to avoid it and integrity in
6 science and what the best way is to work with data
7 to make sure that it is presented in the most
8 objective, honest way. So -- and, of course, we
9 critiqued papers in that -- in that class where
10 the students would read research papers and we
11 would go through and critique them. I would have
12 this -- I would lead the students and -- and teach
13 them. And then I would have them do presentations
14 on topics so they got some experience putting
15 presentations together. And then the other
16 students in the class would question them and
17 challenge them on different ideas.

18 **Q. You mentioned earlier that you**
19 **had funding for your research. You mentioned**
20 **corporate sponsors, correct?**

21 A. Yes.

22 **Q. And who were those corporate**
23 **sponsors?**

24 A. I have gotten some funding early
25 in my career from -- from -- can I -- is it okay

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1 if I look at my CV --

2 **Q. Sure.**

3 A. -- which we have up here? Okay.

4 **Q. Yes.**

5 A. Okay. So early in my career I
6 received a grant from a company called Humanetics
7 Corporation to -- it was a very small grant of
8 less than \$4,000 to look at the effect of a
9 particular compound on DNA synthesis in mouse
10 melanoma cells. So that was a very, very small in
11 vitro study which was early in my career.

12 I also have more recently
13 received funding through my work as director of
14 the Healthy Food, Healthy Lives Institute from the
15 Cargill Foundation, and that grant was an
16 education grant, the purpose of which was to bring
17 high school students to the university to
18 introduce them to food and agriculture careers.
19 It was a trial -- it's a -- it's a project, the
20 purpose of which is to bring more diversity to
21 food and agriculture which we have unfortunately
22 an unacceptably low rate of -- of diversity within
23 the field. And so the purpose of that study is to
24 try to introduce students who might not think
25 about it as a career to come to the university and

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1 get to know it a little bit. So that was from
2 Cargill. Those are the only ones I can really see
3 on my résumé.

4 I've also had some foundation
5 support from the -- the Susan -- the Susan G.
6 Komen Foundation and -- and then some -- a few
7 other sources, state funds, et cetera. But as you
8 can see from my CV, it's mainly federal funding.

9 **Q. I believe you mentioned soy as**
10 **one of the products that was involved that you**
11 **focused on during your clinical research?**

12 A. Yes.

13 **Q. Are there any other products or**
14 **ingredients that were -- that were involved in**
15 **your research?**

16 A. Yes. So I would say that for
17 much of my career I focused on the health effects
18 of soy consumption. I also have looked at the
19 health effects of consumption and flaxseed and
20 green tea extract. I was a collaborator on a
21 project looking at omega-3 fatty acids and on
22 another project looking at the interaction between
23 soy and seaweed. And I've done a study looking at
24 the interaction between soy and probiotics. So
25 I've looked at probiotics as well in my own

35

1 research. And then, as I said, the collaborative
2 project was on soy and bone health, and I've done
3 quite a few collaborative projects further looking
4 at flaxseed.

5 **Q. Have you ever conducted any**
6 **research involving Prevagen?**

7 A. No, I have not.

8 **Q. Have you ever conducted any**
9 **research involving apoaequorin?**

10 A. I have not, no.

11 **Q. Have you ever been involved in**
12 **research involving vitamin D?**

13 A. No, I have not.

14 **Q. Your CV also mentions some work**
15 **involving journals. Could you describe that,**
16 **please?**

17 A. I have acted as a reviewer for
18 many, many scientific journals, nutrition
19 journals. I am contacted a few times a month to
20 review papers, so I've done quite a few peer
21 review of manuscripts. In addition, I have served
22 as a member of the editorial board for the Journal
23 of Nutrition, which is one of the premier journals
24 in nutrition, and the Journal of the Society of
25 Nutritional Sciences, which is the American

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1 Society of Nutrition.

2 Currently I am -- I am an
3 academic editor for another society journal called
4 Current Developments in Nutrition which -- which
5 is an open-access online journal of the American
6 Society of Nutrition. And because of the work
7 that I've done in Native American communities with
8 scholarship involving work with triable
9 communities, I helped launch a new section in that
10 journal on the food and nutrition of indigenous
11 peoples, and I'm the academic editor for that
12 section. In that role, I supervise the peer
13 review of any papers that come through on that
14 topic. So I assign reviewers, I read their
15 reviews, and I make the final decision about
16 publication, whether or not the paper needs to
17 be -- needs to be revised and whether or not the
18 paper can be published.

19 **Q. Okay. Have you ever been**
20 **involved in any academic journals that focused on**
21 **cognitive function?**

22 A. No, I have not.

23 **Q. Your CV also mentioned you were**
24 **involved in some professional organizations.**
25 **Could you describe that involvement, please?**

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1 A. I've been involved with my main
2 professional society which is, as I said, the
3 American Society for Nutrition. I have served on
4 the graduate education committee of that
5 organization. I have served on a couple of
6 different award committees. And I was -- last
7 year, the year before, I was elected as a fellow
8 of the American Society of Nutrition which is a
9 limited group of people. It's not an automatic
10 thing. Only about five to ten or so people per
11 year are elected to be fellows of that society.

12 **Q. Have you ever been involved any**
13 **professional organizations that involve cognitive**
14 **function?**

15 A. I have not.

16 **Q. And except for the article you**
17 **drafted involving mood, have you ever been**
18 **involved in any other articles that involve any**
19 **aspect of cognitive function?**

20 A. No, I have not to my knowledge.
21 I don't recall any.

22 **Q. In your professional career,**
23 **have you ever evaluated someone's cognitive**
24 **function?**

25 A. No, I have not.

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1 **Q. Do any of the articles listed on**
2 **your CV involve vitamin D?**

3 A. No, they do not.

4 **Q. Dr. Kurzer, what areas do you**
5 **consider yourself to be an expert in?**

6 A. I'm an expert in nutritional
7 science. This is what my Ph.D. is in. Nutritional
8 science is a combination really of biochemistry
9 and physiology as they apply to nutrients. And so
10 this is my general area of expertise.

11 I teach basic nutrition, and so
12 I'm in a position to keep up with the literature
13 in nutrition and -- and so I would say that that's
14 my general area of expertise.

15 I have more specific subareas of
16 expertise which include dietary supplements, which
17 include reproductive hormones and their
18 interaction with -- with nutrition. I have done a
19 great deal of work on the nutrition of women and
20 gender differences and sex differences in response
21 to nutrition, and that's another area of expertise
22 for me. Cancer prevention is another subarea of
23 interest to me.

24 So within the general area of
25 nutritional science, I have these subareas of

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1 expertise. And then --

2 **Q. Any other --**

3 A. -- clinical -- clinical trials
4 in nutrition. I consider myself an expert on
5 that.

6 **Q. Anything else?**

7 A. Those are the main areas.
8 Something else may come up again.

9 **Q. So you don't consider yourself**
10 **to be an expert in cognitive function, correct?**

11 A. I -- in -- in my professional
12 capacity, no.

13 **Q. Do you consider yourself to be**
14 **an expert in statistics?**

15 A. I consider myself to be an
16 expert in utilizing statistics in the -- in the --
17 in the context of nutrition studies. I've worked
18 very closely with statisticians. I have -- I have
19 not done very many statistical analyses on my own
20 because I don't have a Ph.D. or formal training in
21 statistics other than a series of classes that I
22 took as a graduate student. So in every study
23 that I have ever worked on, I've worked very
24 closely with statisticians. I have never just
25 handed the data over to them, asked them to

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1 analyze it and send it back to me. I always
2 discuss with them various techniques, methods. We
3 argue back and forth. I might recommend something
4 else. They agree or don't and tell me why.

5 So I've been heavily involved in
6 most of the statistical analyses for my research,
7 although I would not say that I'm the primary
8 driver. I'm the primary driver of the -- the --
9 the design of the study, the analytical work, the
10 biochemical work, et cetera. But I work with
11 others who have Ph.D.s in biostatistics.

12 **Q. And I take it you've never done**
13 **any research in the area of biostatistics?**

14 A. That's correct, I have not.

15 **Q. And have you ever taught any**
16 **classes on biostatistics?**

17 A. I have taught classes that
18 included sections on biostatistics. So as a
19 graduate student, I was a teaching assistant in a
20 laboratory class in which we had the students do
21 statistical analyses. And I recall having the
22 students do an analysis of variance by hand. So
23 they had to do all of the calculations by hand
24 because it's -- it was extremely important to me,
25 and it still is, that students who are in science

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1 don't -- don't use a sort of black box approach to
2 the work that they do. It's very easy to just put
3 data into a computer and it spits out the results,
4 and the person doing it may or may not really
5 understand what the program did. So it was very
6 important to me in that capacity. And I've talked
7 about it also in some of the seminars that I've
8 taught as well and some of the graduate classes,
9 the importance of actual looking at the data and
10 understanding the data, not just putting it into a
11 machine, getting the results out.

12 And -- and so the ideas of
13 statistics and how they're properly used has been
14 a thread throughout my career, something very
15 important. So I've never taught a statistics
16 course.

17 But in the context of all of the
18 other things I teach, for example, in -- even in
19 my introductory class I teach the students how to
20 evaluate information because, as you can imagine,
21 we are bombarded with so much nutrition
22 information from the internet. Before computers,
23 it was from magazines and newspaper articles and
24 advertisements and radio and -- and so now it's
25 computers. And students don't understand how to

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1 evaluate the data that they see, which one should
2 they believe, this magazine article or this
3 professor. And so I talk a little bit about
4 statistical analyses and how important that is and
5 how important it is to understand how to interpret
6 statistics and how statistics can be interpreted
7 in numerous ways. So I do talk about it in my
8 courses, although it is not the primary focus of
9 my teaching.

10 **Q. Are you involved in any**
11 **professional organizations relating to statistics?**

12 A. No, I am not.

13 **Q. Have you ever been involved in**
14 **any academic journals that focus on biostatistics?**

15 A. No, I have not.

16 **Q. Earlier today we -- we -- you**
17 **mentioned protocols in one of your responses.**
18 **Could you describe what a protocol is?**

19 A. A protocol is the detailed
20 description of what is going to be done in an
21 experiment. So in a protocol, the methods that
22 are going to be used are described, the -- in a --
23 in a human study. There are many various things
24 that could be described, including what the
25 subject study population is going to be, inclusion

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1 and exclusion criteria, et cetera, how the data --
2 how the samples are going to be analyzed, what
3 they're going to be analyzed for. If it's an
4 animal experiment, how many animals there are
5 going to be, et cetera. And so it's a -- it's a
6 map. It's a map of how to go about doing the
7 research.

8 **Q. And what do people conducting**
9 **the clinical trial use the protocol for?**

10 MS. METZINGER: Objection to
11 form.

12 You can answer, Dr. Kurzer, if
13 you understand the question.

14 THE WITNESS: Okay.

15 The protocol is used, as I said,
16 as a map, as a basic skeleton for
17 conducting the study.

18 BY MR. WONE:

19 **Q. And is RCT another -- an**
20 **abbreviation from randomized control trial?**

21 A. Yes. It is a randomized control
22 trial, yes.

23 **Q. And so today I'm going to use**
24 **RCT as an abbreviation when I'm referring to**
25 **randomized control trials.**

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1 A. Okay. Sure.

2 **Q. Did the RCTs you were involved**
3 **in use protocols?**

4 A. Yes.

5 **Q. And would the RCTs you were**
6 **involved in follow the protocol?**

7 MS. METZINGER: Objection to
8 form.

9 THE WITNESS: The RCTs that I've
10 been involved in, the -- for the RCTs
11 that I've been involved in, the
12 protocols were written in the context
13 of a grant application. And so they
14 were written for the reviewers to
15 understand what -- what we were going
16 to do for purposes of decision about
17 whether or not to fund the project. So
18 we followed the protocol as best we
19 could, but there are always changes to
20 the protocol that happen during the
21 clinical trial because the actual
22 reality of what happens once you start
23 may be slightly different from the
24 theoretical framework that you've
25 established. So that very often will

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1 vary from the protocol, the initial
2 protocol.
3 BY MR. WONE:
4 **Q. And when you varied from the**
5 **initial protocol, were there any -- were there any**
6 **future updates to the protocol?**
7 MS. METZINGER: Objection to
8 form.
9 THE WITNESS: Sometimes we would
10 update the protocol, but we wouldn't
11 necessarily have a -- we wouldn't have
12 to report back to the funding agency.
13 So there wasn't -- we -- we didn't have
14 to have a formal document that was
15 updated. That was not necessary and
16 not required.
17 BY MR. WONE:
18 **Q. Would you ever mention any of**
19 **the changes that were made in the -- in the**
20 **future -- in the later study reports?**
21 MS. METZINGER: Objection to
22 form.
23 THE WITNESS: If I considered
24 them to be extremely important, I would
25 mention them. But I would not

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1 necessarily mention other -- it
2 would -- I -- it was my judgment to
3 decide whether or not I thought it was
4 substantive enough -- substantive
5 enough to be mentioned. So it depended
6 on the study and it depended on the
7 variation from the protocol.
8 BY MR. WONE:
9 **Q. Could you give an example of**
10 **something you would consider substantive enough to**
11 **warrant mentioning?**
12 MS. METZINGER: Objection to
13 form.
14 THE WITNESS: An example might
15 be the study population in -- I have
16 performed clinical trials in which it
17 was very difficult to recruit
18 participants, and so we had to expand
19 our recruitment network from what we
20 had originally proposed and we had to
21 go to other clinics and other sites and
22 use other mechanisms for recruitment
23 other than what we had put in the
24 protocol. And so we did report that.
25 When -- every year when I write

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1 an annual report to NIH for their --
2 for their records, one of the things
3 that they ask is have there been
4 substantive changes to the protocol,
5 and I would put the change to the
6 protocol in that report if it was
7 substantive.
8 BY MR. WONE:
9 **Q. So would a protocol from an RCT**
10 **identify who the participants or who the study**
11 **population would be?**
12 MS. METZINGER: I'm sorry. Can
13 you repeat that, Mr. Wone?
14 BY MR. WONE:
15 **Q. Would an RCT protocol identify**
16 **who the study participants would be?**
17 MS. METZINGER: Objection to
18 form.
19 THE WITNESS: Yes, the protocol
20 will identify the study participants.
21 BY MR. WONE:
22 **Q. And would the protocol describe**
23 **the study design?**
24 A. Yes, the protocol will describe
25 the study design, but there are many, many levels

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1 of detail. So a protocol can describe it in much
2 less design or in much less detail or much greater
3 detail. So, for example, I've written grants
4 where there was a page limit on the grant
5 application, and so I was limited in what I
6 could -- how much detail I could put in. So I had
7 to select which -- which points I wanted to put
8 into that protocol and which I would leave out.
9 **Q. Did you ever write any protocols**
10 **that were not for a grant -- in connection with a**
11 **grant application?**
12 A. I think that all of my protocols
13 have been in connection to grant applications.
14 And as I -- as I -- I would have to look in great
15 detail at all of my studies, but I'm pretty sure
16 that they were virtually all in relation to grant
17 applications.
18 **Q. So focusing on the instances**
19 **where you didn't have a page limitation for the**
20 **protocol, did those protocols provide details**
21 **about the study design?**
22 A. Yes. And -- and there's always
23 a page limitation. So there's no such thing as no
24 page limitation. Sometimes you have lots more
25 pages than other times. But even for NIH where

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1 there is a greater page limit than for some of the
2 other agencies, you're still -- you still have to
3 keep your study design within -- within a small
4 enough number of pages so that you can write the
5 rest of -- the rest of what you need to write
6 within the page limit. So the -- I -- I put as
7 much detail as I can fit into that -- into that
8 grant application.

9 **Q. And the protocols you worked on,**
10 **would they also describe the treatment that was**
11 **being administered in the study?**

12 A. Yes.

13 **Q. And the protocols you've written**
14 **for RCTs, would they also describe the measures**
15 **that would be used to evaluate efficacy?**

16 A. Yes.

17 **Q. Would the protocols that you've**
18 **written for RCTs also describe the screening**
19 **criteria for participants?**

20 A. Yes.

21 **Q. And so there would be inclusion**
22 **criteria?**

23 A. Yes.

24 **Q. As well as exclusion criteria?**

25 A. Yes.

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1 **Q. And would participants that**
2 **don't meet the screening criteria be excluded from**
3 **the studies you've worked on?**

4 MS. METZINGER: Objection to
5 form.

6 THE WITNESS: In general they
7 would. But it's not always possible to
8 make sure of that. I've had instances
9 where, for example, I was recruiting
10 postmenopausal women. And after I
11 looked at the data and had measured
12 hormones, I realized that some of them
13 were not actually postmenopausal. And
14 so they had to be eliminated from the
15 data analysis because in the end it
16 turned out they didn't fit the original
17 criteria. So I analyzed the
18 participants who fit what I was most
19 interested in, but in recruiting I
20 actually recruited other people as
21 well.

22 BY MR. WONE:

23 **Q. In the RCTs you've worked on,**
24 **did the protocol describe the control?**

25 A. Yes.

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1 **Q. And what kind of details would**
2 **it provide about the control?**

3 MS. METZINGER: Objection to
4 form.

5 THE WITNESS: I would say the
6 detail about the control would be much
7 less than the detail about the
8 treatment. I might just have a
9 sentence or two about the control being
10 used.

11 BY MR. WONE:

12 **Q. And in the RCTs you've worked**
13 **on, would the protocol describe the blinding?**

14 MS. METZINGER: Objection to
15 form.

16 THE WITNESS: I would say that
17 we don't necessarily describe the
18 blinding. We say that it will be
19 blinded but don't necessarily describe
20 in detail what that -- how we're going
21 to make sure that that happens. There
22 is an assumption, I would say, that
23 folks know what blinding means, and so
24 we don't have to say in great detail
25 this is exactly what we're going to do

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1 to make sure that things are blinded.
2 We say it's going to be double-blind or
3 single-blind, and that's really what
4 we -- all we'd have to say. It's not
5 necessary to describe it in more detail
6 than that.

7 BY MR. WONE:

8 **Q. For the RCTs you worked on,**
9 **would the protocol describe whether there was any**
10 **randomization used?**

11 A. Yes.

12 **Q. And would it describe how the**
13 **randomization was to occur?**

14 A. In some cases it would. I think
15 for -- for an NIH grant where a great deal of
16 detail is required, I would probably have put
17 details about the kind of randomization that I was
18 going to use. But I know that I've written other
19 grants and I've written other protocols where I
20 said that they were going to be randomized but not
21 necessarily -- I didn't necessarily describe the
22 technique that I was going to use to perform that
23 randomization.

24 **Q. In the RCTs you worked on, would**
25 **the protocol describe the ratio of participants in**

53

1 **the treatment group to the ratio of -- to the**
2 **participants in the placebo group?**

3 A. I'm not sure what you're asking,
4 Mr. Wone. Can you maybe rephrase that a little
5 bit? I'm not sure what --

6 **Q. Sure.**

7 A. -- you mean by "ratio."

8 **Q. For example, if there was to be,**
9 **you know, 4 to 2 or something like that, so 4 to 2**
10 **in terms of participants and treatment versus**
11 **placebo and it wasn't just 1 to 1, is that**
12 **something that the protocol would describe?**

13 A. I have not done those kinds of
14 studies. My studies have always had an equal
15 number of people in each group.

16 **Q. Have you ever used**
17 **stratification in any of your RCTs?**

18 A. Yes.

19 **Q. And can you describe what**
20 **stratification is?**

21 A. Stratification is -- if -- if
22 I'm understanding your use of the word, my
23 interpretation of your -- of stratification is
24 looking at particular groups of people. For
25 example, if body weight -- if we think that body

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1 weight is an important co-variable, we might
2 stratify the data on the basis of -- of obesity,
3 let's say, you know, average of normal weight,
4 underweight, overweight, or percentages of
5 overweight, and we might look at the data
6 differently in each of those groups because we
7 suspect that the responses will differ on the
8 basis of the participants belonging in those
9 stratifications.

10 **Q. And would the -- in the RCTs you**
11 **worked on, would the protocol describe any**
12 **stratification?**

13 A. Sometimes they would. If we
14 think about it in advance, we would say that the
15 data will be stratified in this kind of way. But
16 sometimes we decide to do that after the fact
17 because while we're doing the trial, we realize
18 that, you know, information -- information comes
19 up during trials especially if they're long
20 trials. I've done a trial that took five years.
21 And it is very limiting to force yourself to stick
22 to the knowledge that you had on that -- on --
23 during that week when you submitted that protocol.
24 It's very important to use the most up-to-date,
25 current information and be flexible. And so we

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1 have stratified data after the fact when we
2 realized that this might be a variable that's very
3 important to look at differently in -- you know,
4 to see if the effect is different based on this
5 co-variable.

6 **Q. And when you stratified after**
7 **the fact, was it after you analyzed the study**
8 **data?**

9 MS. METZINGER: Objection to
10 form.

11 MR. WONE: I'll rephrase that.

12 BY MR. WONE:

13 **Q. In the instances where you've**
14 **stratified after the fact, was it after the study**
15 **had concluded?**

16 A. Yes, it was after the study had
17 concluded because we don't usually -- we're --
18 we're so busy while the study is being conducted
19 that all we can do is problem solve and deal with
20 recruitment and making sure the subjects are
21 compliant and collecting the samples. It's an
22 enormous amount of work to conduct these clinical
23 trials. And so we usually then think about the
24 statistical analysis, yes, after the study is
25 done. The data -- the samples may not have been

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1 analyzed yet. So if we're collecting biological
2 samples such as -- such as urine or blood,
3 et cetera, we don't necessarily have those data
4 yet. But we think about -- we -- we think more
5 deeply about the statistics before we perform them
6 at the end of the study, and we may make some
7 changes.

8 **Q. And is stratification something**
9 **you would discuss with the biostatistician that**
10 **you worked with to analyze the data?**

11 A. Yes, I would.

12 **Q. Have there ever been any**
13 **instances where you stratified the data after you**
14 **had already started analyzing it?**

15 MS. METZINGER: Objection to
16 form.

17 THE WITNESS: I don't recall
18 any. I'd have to look at the
19 individual papers themselves and -- you
20 know, because my career goes back
21 30 years. So I would have to really
22 look at data to be able to analyze it,
23 to be able to answer that question.

24 BY MR. WONE:

25 **Q. If an RCT was going to have**

<p style="text-align: right;">57</p> <p>1 subgroups, is that something that would be</p> <p>2 identified in the protocol?</p> <p>3 MS. METZINGER: Objection to</p> <p>4 form.</p> <p>5 THE WITNESS: Can you rephrase</p> <p>6 that question, please?</p> <p>7 BY MR. WONE:</p> <p>8 Q. Sure.</p> <p>9 If a study was going to focus on</p> <p>10 a particular subset of the entire study</p> <p>11 population, is that something that would be</p> <p>12 identified in the protocol?</p> <p>13 MS. METZINGER: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: It might be</p> <p>16 identified or it might not be because</p> <p>17 if it's something that we think about</p> <p>18 in advance, then it would be in the</p> <p>19 protocol. But if it's something that</p> <p>20 comes up during the conduct of the</p> <p>21 study which, as I said, could take a</p> <p>22 very long time, then it might be</p> <p>23 something that we decide to do after</p> <p>24 the protocol is written originally.</p> <p>25 And this is -- this is extremely</p>	<p style="text-align: right;">59</p> <p>1 form.</p> <p>2 THE WITNESS: I would say both,</p> <p>3 that it could be -- some of it would</p> <p>4 have come up during the study and some</p> <p>5 of it might have come up after the</p> <p>6 study. But it would not have come up</p> <p>7 after we analyzed the data and looked</p> <p>8 at it and then decided, okay, now we're</p> <p>9 going to do some other additional</p> <p>10 things. This is something that would</p> <p>11 have come up before we knew what the</p> <p>12 primary results were.</p> <p>13 BY MR. WONE:</p> <p>14 Q. Okay. And would the study</p> <p>15 protocol -- strike that.</p> <p>16 For the RCTs you worked on,</p> <p>17 would the protocols describe when the</p> <p>18 interventions were to be given?</p> <p>19 A. Yes.</p> <p>20 Q. And would the protocols describe</p> <p>21 how long the study period is going to be?</p> <p>22 A. Yes.</p> <p>23 Q. And would the study protocols</p> <p>24 state when the testing of the participants was to</p> <p>25 occur?</p>
<p style="text-align: right;">58</p> <p>1 important to remember, that clinical</p> <p>2 trials are incredibly expensive,</p> <p>3 incredibly difficult to do, and time</p> <p>4 consuming for many, many, many people.</p> <p>5 And so we try to get as much</p> <p>6 information.</p> <p>7 My -- my green tea clinical</p> <p>8 trial cost \$5 million or \$6 million,</p> <p>9 and we felt that it was extremely</p> <p>10 important to try to get as much</p> <p>11 information from this population as</p> <p>12 possible. And so as information about</p> <p>13 the -- about green tea developed in the</p> <p>14 course of the study, things came up</p> <p>15 that we realized we could look at that</p> <p>16 we hadn't thought about in advance.</p> <p>17 And it would be, I think, neglectful to</p> <p>18 not pursue those additional</p> <p>19 opportunities.</p> <p>20 BY MR. WONE:</p> <p>21 Q. And the things that came up</p> <p>22 during the green tea study, was it while the study</p> <p>23 was ongoing or after the study had already</p> <p>24 concluded?</p> <p>25 MS. METZINGER: Objection to</p>	<p style="text-align: right;">60</p> <p>1 A. Yes.</p> <p>2 Q. And should the protocol identify</p> <p>3 the outcome measures being used to evaluate</p> <p>4 efficacy?</p> <p>5 MS. METZINGER: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: The protocol would</p> <p>8 identify the outcome measures as we saw</p> <p>9 them at the time of writing the</p> <p>10 protocol, but we very often would add</p> <p>11 and modify that as the study goes along</p> <p>12 as we realize that there may be other</p> <p>13 indicators of efficacy that we had</p> <p>14 neglected to put into the protocol that</p> <p>15 were important and would be very</p> <p>16 valuable information to have. So we</p> <p>17 might modify that -- those.</p> <p>18 BY MR. WONE:</p> <p>19 Q. And if you were to modify the --</p> <p>20 the measures, is that something you would consider</p> <p>21 to be a substantive change and would later report</p> <p>22 to an NIH report?</p> <p>23 A. Yes, I would add that we have</p> <p>24 expanded our aims to include additional questions</p> <p>25 and additional endpoints.</p>

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1 **Q. And after -- if after the study**
 2 **had started, before you analyzed the data you were**
 3 **to -- you mentioned you sometimes change the**
 4 **stratification. Is that also something you would**
 5 **consider a substantive change to be reflected in**
 6 **a -- in an NIH report?**

7 MS. METZINGER: Objection.

8 MR. de LEEUW: Objection.

9 THE WITNESS: I would not
 10 necessarily put that in an NIH report,
 11 but it would go into the results of the
 12 study and when I report the results.
 13 But I wouldn't feel a need to put that
 14 kind of a change into an interim report
 15 to NIH, an annual report, no. They
 16 don't care about that kind of stuff.
 17 They're not that interested in it.
 18 They wouldn't -- they're -- they're
 19 more interested in -- you know, that I
 20 accomplish what I initially said that I
 21 was going to.

22 BY MR. WONE:

23 **Q. And if you were to make any**
 24 **changes to the subgroups that -- that weren't in**
 25 **the original protocol, is that something you would**

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1 **consider a substantive change and would include it**
 2 **in an NIH report?**

3 MS. METZINGER: Objection to
 4 form.

5 THE WITNESS: No, I would not --
 6 I would -- again, I would -- that would
 7 be part of the results that we
 8 reported. But it would not be
 9 considered a change in the study
 10 design.

11 BY MR. WONE:

12 **Q. For the RCTs you've worked on,**
 13 **did the protocols include a statistical analysis**
 14 **plan?**

15 A. Yes.

16 **Q. And have there ever been any**
 17 **instances where you made any changes later to the**
 18 **statistical analysis plan?**

19 MS. METZINGER: Objection to
 20 form.

21 THE WITNESS: There may have
 22 been. I really don't recall at the
 23 moment. Again, I'd have to look at my
 24 work in great detail to be able to
 25 answer that question.

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1 BY MR. WONE:

2 **Q. And would you consider a change**
 3 **to how you analyze the data to be a substantive**
 4 **change?**

5 MS. METZINGER: Objection to
 6 form.

7 THE WITNESS: It depends on what
 8 the change is. I can't make a blanket
 9 statement on that.

10 BY MR. WONE:

11 **Q. Have you ever heard someone**
 12 **describe a change being made to an RCT as post**
 13 **hoc?**

14 A. Yes.

15 **Q. And what is your understanding**
 16 **of what post hoc means in that context?**

17 A. Post hoc is -- my understanding
 18 of the use of the term "post hoc" in this context
 19 is that it is analyses that are done that were not
 20 planned, preplanned, that were decided after the
 21 study was -- was complete.

22 **Q. Do you believe it's important to**
 23 **distinguish when an analysis has been**
 24 **predetermined versus post hoc?**

25 MS. METZINGER: Objection to

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1 form.

2 THE WITNESS: I think it depends
 3 on the context. There are situations
 4 in which it's important because of
 5 the -- for example, if you're
 6 submitting a paper to a very, very
 7 rigorous journal, they might insist on
 8 that kind of clarification. But
 9 certainly there are many studies, many,
 10 many, many studies published that do
 11 not declare if an analysis is post hoc
 12 or not. So, you know, it really
 13 depends on where the publication is
 14 going to be and what the context is.

15 BY MR. WONE:

16 **Q. And do you know why those**
 17 **rigorous publications insist on identifying a**
 18 **particular change as post hoc?**

19 MS. METZINGER: Objection to
 20 form.

21 THE WITNESS: I believe that
 22 it's because in the strictest sense of
 23 using statistics, when statistics are
 24 interpreted very narrowly and strictly,
 25 that it is considered best practice to

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1 identify what your hypothesis was up
2 front and what you might have changed
3 or added afterwards in order to avoid
4 the perception or -- that a -- that a
5 researcher might be doing what might be
6 called data mining, et cetera, which is
7 not considered good practice.

8 But there are many, many, many
9 researchers who do not necessarily
10 declare if something was post hoc and
11 they are not data mining. There is no
12 data mining. They are with good
13 conscious and with great integrity,
14 they are realizing that there are other
15 endpoints that are important, and so
16 they report on them, which I think in
17 many cases and in most cases is good
18 practice.

19 BY MR. WONE:

20 **Q. When you are evaluating a study,**
21 **how do you know what the results are, the product**
22 **of data mining versus someone who had found**
23 **something new?**

24 MS. METZINGER: Objection to
25 form.

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1 THE WITNESS: Very often it's
2 not -- it -- it -- I don't believe it's
3 always possible to tell. There may be
4 researchers who -- who do data mining
5 and publish papers and don't -- you
6 know, and they don't say anything about
7 it. And so I suspect that it's done
8 quite a bit and we don't -- we just
9 don't know about it.

10 BY MR. WONE:

11 **Q. In the context of an RCT, are**
12 **you familiar with the term "statistically**
13 **significant"?**

14 A. Yes.

15 **Q. And what does it mean when the**
16 **results of an RCT are statistically significant?**

17 A. A p-value is -- is chosen, and
18 usually the p-value is .05. And if a statistical
19 test is performed which shows that the -- that the
20 product that you're studying or the treatment is
21 effective at the level of .05, it achieves
22 significance, that means that there's only a
23 5 percent chance that the results were due to
24 random effects. So it's a -- it's a mathematical
25 technique to determine probability -- the

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1 probability that your results are true versus they
2 occurred by chance.

3 **Q. And when evaluating clinical**
4 **studies, is statistical significance something you**
5 **look for?**

6 A. Yes, it is. But it isn't the
7 only thing I look for. I look for statistical
8 significance along with other things as well.

9 **Q. And what are some of those other**
10 **things? What are the other things you look for?**

11 A. I always look at the data. I
12 always, with my own studies, graph the data so
13 that I can see exactly what's happened in a visual
14 reputation, and I always look at trends. And the
15 reason I always look at trends is because in human
16 studies, there are so many variables affecting
17 outcomes, many of which we don't know.

18 So we control for the variables
19 that we know about. But there are many, many,
20 variables that we don't know about because we're
21 discovering new ones all the time.

22 So you can see in studies, for
23 example, in population studies, epidemiological
24 studies, the data may be controlled for five to
25 ten different variables that they think may be

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1 affecting the endpoint. And there are many that
2 we don't know about.

3 And so the -- everything is
4 stacked against our ability to see a true result.
5 It's very, very difficult in human studies, in
6 clinical studies as opposed to in vitro studies or
7 animal studies where you can, you know, lock these
8 creatures up in a box and control everything in
9 their environment.

10 With humans, particularly if
11 they're free living, there are so many things that
12 we can't control that it's very, very difficult to
13 get a highly significant, statistically
14 significant result.

15 So in my opinion and the opinion
16 of a number of my colleagues and many
17 statisticians who I've work with, it is important
18 to talk about trends because sometimes you may not
19 be -- you may not have enough statistical power to
20 achieve significance. But if the trends of a
21 number of endpoints are in the same direction,
22 that -- that is meaningful and that is worth
23 reporting.

24 MS. METZINGER: Mr. Wone, we've
25 been going for just about an hour and a

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1 half. I don't need to take a break at
2 this moment, but I think we should
3 think about taking one in the next few
4 minutes if you get to a natural point.

5 MR. WONE: Yeah, I've got a
6 couple more questions. But, yeah, we
7 can take a break after that.

8 MS. METZINGER: Okay. Thank
9 you.

10 BY MR. WONE:

11 **Q. When you're looking at data, how**
12 **do you weigh the trends versus data that's**
13 **statistically significant?**

14 MS. METZINGER: Objection to
15 form.

16 THE WITNESS: That's a difficult
17 question to answer because statistical
18 significance, of course, is considered
19 the sort of, you know, kind of proof in
20 a way to some degree. But in my
21 opinion, it's very narrow. The choice
22 of .05 is an arbitrary choice. And
23 even statisticians will agree to that.
24 And the American Statistical Society
25 agrees that .05 is -- is an arbitrary

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1 cutoff. Why not .01 or why not .1?

2 I have worked with statisticians
3 who did a lot of clinical trial work
4 who told me that they felt that for
5 clinical studies a p-value of .1 or .2
6 even should be used because of all of
7 the variability that makes it so
8 difficult to get a statistically
9 significant result with a .05 cutoff.

10 So, therefore, I consider the --
11 the showing of trends to be very, very
12 important, and I very often will report
13 trends along with significance.

14 So I can't say that one is more
15 important than the other or that one
16 would invalidate the other. I would
17 look at them together. And I would
18 look at the p-values and the trends in
19 the context of the p-values and, you
20 know, if -- if there are p-values that
21 show no -- many -- if there are -- if
22 my statistical analysis shows across
23 the board nothing but then I show some
24 trends, depends on how strong the
25 trends are. If the trends are weak

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1 trends, then I wouldn't value them as
2 much as I would strong trends. If the
3 trends occur with a number of
4 endpoints, that would be more valuable
5 than if the trends occur with just a
6 couple of endpoints.

7 So, again, it's looking -- it's
8 standing back and looking at the whole
9 picture. That's how -- that's my
10 approach to working with data, is that
11 I -- I try not to be very narrow and
12 try to be a little bit more broad in my
13 thinking and -- in what I present.

14 BY MR. WONE:

15 **Q. Do you use a p-value of .05 in**
16 **your research?**

17 A. Yes, I do. I use a p-value of
18 .05 because that is the -- the most widely
19 accepted p-value. But my way of dealing with that
20 is to show trends. So I don't change the p-value
21 because I have no way of knowing what I should
22 change it to. It's all arbitrary.

23 **Q. And in the context of an RCT,**
24 **have you heard the term "clinical significance"?**

25 A. Yes.

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1 **Q. And what is your understanding**
2 **of what clinical significance means?**

3 A. Clinical significance as opposed
4 to statistical significance refers to the -- the
5 importance with respect to health, disease, and
6 the biological endpoints that you're talking about
7 as opposed to the significance of the numbers on
8 paper.

9 **Q. Is it possible for something --**
10 **for a result to be statistically significant but**
11 **not clinically significant?**

12 MS. METZINGER: Objection to
13 form.

14 THE WITNESS: Yes, it is. It is
15 possible. It's certainly possible, but
16 I would qualify that by saying that
17 there are very often arguments about
18 that among clinicians so that there
19 might be some clinicians who would say
20 it's an important result and others who
21 say that it's not clinically
22 significant. So, yes, that does occur.

23 BY MR. WONE:

24 **Q. And what camp do you find**
25 **yourself falling in? Do you believe that every**

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1 **change is clinically significant?**

2 MS. METZINGER: Objection to
3 form.

4 THE WITNESS: I am not an expert
5 on -- I'm not a clinician myself. I'm
6 not an expert on clinical significance,
7 so I wouldn't be able to comment on
8 that.

9 BY MR. WONE:

10 **Q. And so in the research that**
11 **you've conducted, how do you determine whether the**
12 **statistically significant results were clinically**
13 **significant?**

14 MS. METZINGER: Objection to
15 form.

16 THE WITNESS: It hasn't always
17 come up in my research, but there have
18 been a few times when it has come up.
19 And in that -- in those times, I often
20 have clinical collaborators who help me
21 interpret the clinical significance
22 of -- of the result.

23 BY MR. WONE:

24 **Q. So if I remember right, you did**
25 **some research focusing on endpoints related to**

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1 **cancer?**

2 A. Yes.

3 **Q. And so if there was an issue of**
4 **clinical significance, you would consult with**
5 **someone who has -- who considers himself an expert**
6 **in cancer? Is --**

7 A. Yes.

8 **Q. -- that what you mean?**

9 THE WITNESS: Yes.

10 MS. METZINGER: Objection to
11 form.

12 THE WITNESS: But -- but I
13 wouldn't -- I must -- I must say -- I
14 must add to that, Mr. Wone, that that
15 isn't something that I consider to be
16 necessary. Very often there are not
17 clinicians who are part of research
18 teams and papers. Data can be
19 published, and then it's up to the
20 readers to reach their own conclusions.
21 And so readers then have the
22 opportunity to interpret the
23 significance, the clinical significance
24 of the results.
25

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1 BY MR. WONE:

2 **Q. So you would publish the data**
3 **without saying one way or the other whether you**
4 **thought it was clinically significant?**

5 A. That's right. That is exactly
6 right. I wouldn't always talk about the clinical
7 significance. And most scientists -- many
8 scientists do not. And then that becomes a topic
9 for conversation in the scientific community.

10 **Q. When you were conducting your**
11 **RCTs on endpoints involving cancer, why did you**
12 **choose to use human clinical trials rather than**
13 **animal studies?**

14 A. Honestly, for me, I mean, this
15 is -- I know this is not what you're asking, but I
16 have much more fun with human clinical trials than
17 I do with animal trials. Personally, I don't like
18 killing animals, and so I've never done -- I'm a
19 little bit unique as a scientist in that I've not
20 spent a good portion of my career working on
21 animal studies just because -- I think they're
22 extremely important and they provide very, very
23 critically important data, but personally, I -- I
24 don't want to -- I don't want to chop the head off
25 a rat, you know, and put it in a guillotine, which

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1 is what is done. So I don't do it.

2 But I also think that clinical
3 trials are important. It's -- it's very important
4 in -- in many situations, not all situations, to
5 have verification of results in humans because the
6 results of animal studies may or may not be
7 extrapolatable to humans. So I appreciate the
8 importance of doing human studies.

9 **Q. And would the same be true**
10 **versus for human studies versus in vitro studies,**
11 **the result from an in vitro study may not be -- it**
12 **may not apply to humans?**

13 A. Yes.

14 **Q. And would you agree that if you**
15 **wanted to make a claim about a product having an**
16 **effect in humans, that you would need human**
17 **clinical trials?**

18 MS. METZINGER: Objection to
19 form.

20 THE WITNESS: That actually
21 depends on the situation. I think very
22 often I would agree that human trials
23 are needed, but there are situations in
24 which you can't do human trials. So,
25 for example, with tobacco, with tobacco

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1 effects, it wouldn't be considered
2 ethical to have two groups one of which
3 smokes -- one which you give cigarettes
4 to and the other one you don't.

5 Or cancer trials. It would not
6 be considered ethical to take two
7 groups of people, give one group cancer
8 and the other group no and then see
9 what happens.

10 So there are situations in which
11 it's either not ethical, not feasible
12 too expensive. And, frankly, I think
13 that because of the expense of clinical
14 trials of -- especially the very big
15 clinical trials, they're going to be
16 funded less and less. And, in fact,
17 in -- when you look at NIH funding,
18 they have been funded less and less,
19 and there's more and more research
20 going into developing animal models and
21 alternative models to working with
22 humans because they're so impractical
23 and -- and difficult and expensive to
24 do.

25 MR. WONE: Well, we certainly

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1 don't want to give cancer or heart
2 attacks to anyone.

3 Okay. I think we can take a
4 break here, if that's fine with you,
5 Jaclyn.

6 MS. METZINGER: Sure, that would
7 be great.

8 MR. WONE: Okay. We'll go off
9 the record.

10 THE VIDEOGRAPHER: We are going
11 off the record at 10:09 A.M.

12 (Off the record from 10:09 until
13 10:28.)

14 THE VIDEOGRAPHER: We are going
15 back on the record at 10:28 A.M.

16 BY MR. WONE:

17 **Q. Hello, Mr. Kurzer.**

18 A. Hello.

19 **Q. I just wanted to go back to
20 something we had talked about before the break.
21 Is it possible to have an RCT investigating
22 whether a dietary supplement causes change in
23 memory in humans?**

24 MS. METZINGER: Objection to
25 form.

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1 THE WITNESS: Yes, it is.

2 BY MR. WONE:

3 **Q. When were you retained by the
4 defendants as an expert, Dr. Kurzer?**

5 A. I'm not sure how to answer that.
6 I've been retained for over the course of a number
7 of years because there have been various cases
8 dealing with this issue. So my original -- I was
9 retained originally probably about maybe five to
10 seven years ago. I don't know exactly. I'd have
11 to look it up to see.

12 **Q. And when you were retained five
13 to seven years ago, was it in connection with this
14 case or something else?**

15 A. In connection with -- with -- I
16 guess I'm -- not being a lawyer, I'm not sure how
17 specific about the case that you want to be there.
18 There's been some litigation. There's been -- I
19 have met with the FTC about this previously. I
20 met with some commissioners previously maybe
21 for -- or a few year -- two to three years ago, I
22 think, so -- so there have been -- it's all been
23 related to the same issues but in different
24 contexts as far as the litigation goes.

25 **Q. Have you ever done any work for**

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1 **any of the defendants that was not related to
2 litigation?**

3 MS. METZINGER: Objection to
4 form.

5 THE WITNESS: I'm not sure how
6 to answer that. I -- I don't believe
7 that I have. But, again, I don't
8 understand the technical legal terms,
9 so I'm not exactly sure what the answer
10 to that is.

11 BY MR. WONE:

12 **Q. Have you ever done any research
13 for the defendants?**

14 A. Yes.

15 **Q. What kinds of research?**

16 A. I've done literature reviews as
17 summarized in the report that I've written.

18 **Q. Any other kind of research?**

19 MS. METZINGER: Objection to
20 form.

21 THE WITNESS: I believe that all
22 of my research is summarized in the
23 report.

24 BY MR. WONE:

25 **Q. Have you ever had any**

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1 **communications with any other experts that have**
2 **been retained by defendants in this case?**

3 A. I have not.

4 **Q. Did you review any of the**
5 **reports by any of the other defendants' experts?**

6 A. Yes, I have.

7 **Q. Do you recall which reports**
8 **you've reviewed?**

9 A. I reviewed, I believe, all of
10 the other reports, Dr. Goodman, Dr. Schwartz, I
11 think. I can't -- I've read the FTC reports and
12 the -- the defendants' reports. And so I'm not
13 recalling offhand whose name is which.

14 **Q. Okay.**

15 A. But I believe I've read them
16 all.

17 **Q. Okay. Aside from attorneys**
18 **representing the defendants, have you ever had**
19 **communications with any other person relating to**
20 **your work in this case?**

21 A. No, I have not.

22 MS. METZINGER: Your audio is
23 not coming through, Mr. Wone.

24 MR. WONE: Okay.
25

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1 BY MR. WONE:

2 **Q. Have you ever interacted with**
3 **anyone affiliated with Quincy Bioscience?**

4 MS. METZINGER: Objection to
5 form.

6 THE WITNESS: I don't believe I
7 have. It's possible that someone from
8 Quincy was at the FTC meeting. I don't
9 recall. But that would have been the
10 only interaction, was at that meeting.
11 I have not had other interactions.

12 BY MR. WONE:

13 **Q. And does your report, what's**
14 **been marked as Exhibit MK1, contain a complete**
15 **statement of all of the opinions you're offering**
16 **in this case?**

17 MS. METZINGER: Objection.

18 THE WITNESS: Yes. All of the
19 opinions that I was asked to offer at
20 the time that I wrote my report are
21 present. I may have other opinions in
22 addition to that that aren't in the
23 report.

24 BY MR. WONE:

25 **Q. Did anyone assist you in writing**

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1 **the report?**

2 A. No. I wrote the report myself.

3 **Q. And the other opinions that you**
4 **have you mention that were not in the report, are**
5 **they opinions that you intend to offer that are**
6 **going to be offered in this case by defendants?**

7 MS. METZINGER: Objection.

8 THE WITNESS: They would be
9 opinions that I would offer if I'm
10 asked a question related to them. If
11 I'm asked a question related to
12 something that's not in my report, I
13 will offer the opinion.

14 BY MR. WONE:

15 **Q. In connection with your work in**
16 **this case, did you review any advertising for**
17 **Prevagen?**

18 A. I did, yes.

19 **Q. Do you recall which ads you**
20 **reviewed?**

21 A. I recall reviewing the -- the
22 label in particular. And that's the main thing I
23 can recall right now. I may have reviewed other
24 things, so you may have some documents that if
25 you'd like me to look at them, I can -- I can look

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1 at them.

2 **Q. Okay. Have you ever been**
3 **involved in the marketing of Prevagen?**

4 A. I have not, no.

5 MS. METZINGER: Objection to
6 form.

7 BY MR. WONE:

8 **Q. Do you consider yourself an**
9 **expert in marketing?**

10 A. No, I do not.

11 **Q. Do you consider yourself an**
12 **expert in advertising?**

13 A. No, I do not.

14 **Q. If you'd please go to**
15 **paragraph 8 of your report which has been marked**
16 **as Exhibit MK1.**

17 A. Yes, I see that right here,
18 paragraph 8.

19 **Q. And does paragraph 8 identify**
20 **the claims for Prevagen that you evaluated in this**
21 **case?**

22 A. Yes.

23 **Q. And in paragraph 9, you state**
24 **that the defendants provided you with a definition**
25 **of competent and reliable scientific evidence,**

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1 correct?

2 A. Yes.

3 **Q. Aside from this litigation, is**
4 **that definition, a competent and reliable**
5 **scientific evidence, something you use to**
6 **determine about -- in other -- sorry. Strike**
7 **that.**

8 **Aside from this litigation, have**
9 **you ever used the definition of competent and**
10 **reliable scientific evidence?**

11 MS. METZINGER: Objection to
12 form.

13 THE WITNESS: I have used that
14 in other situations in which I've
15 written expert reports.

16 BY MR. WONE:

17 **Q. Have you ever used that**
18 **definition, "a competent and reliable scientific**
19 **evidence," outside of the litigation context?**

20 A. No, I have not.

21 MS. METZINGER: Objection to
22 form.

23 BY MR. WONE:

24 **Q. Instead of the definition of**
25 **competent and reliable scientific evidence in**

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1 **that you listed in paragraph 8 as the "challenged**
2 **claims," which is the abbreviation that you used.**
3 **Okay?**

4 A. Yes.

5 **Q. Do you believe there's human**
6 **clinical testing that was randomized,**
7 **double-blinded placebo-controlled and conducted by**
8 **qualified researchers to support the challenged**
9 **claims?**

10 MS. METZINGER: Objection to
11 form.

12 THE WITNESS: Yes, I do.

13 BY MR. WONE:

14 **Q. If you could please go to**
15 **paragraph 10, Doctor. It's on the next page,**
16 **page 3 of your --**

17 MR. de LEEUW: You have to keep
18 your voice up. You have to keep your
19 voice up. I don't know if you can
20 adjust your microphone, but --

21 MR. WONE: Sure.

22 MR. de LEEUW: -- sometimes you
23 fade out.

24 MR. WONE: I'll try to move it
25 closer.

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1 **paragraph 9 of your report, if I said the human --**
2 **that competent and reliable scientific evidence**
3 **meant human clinical testing that was randomized,**
4 **double-blinded and placebo-controlled conducted by**
5 **qualified researchers, would it still be your**
6 **opinion that the claims are supported by confident**
7 **and reliable scientific evidence?**

8 MS. METZINGER: Objection to
9 form.

10 THE WITNESS: Could you repeat
11 that question, please, Mr. Wone?

12 (Reporter read back requested
13 material.)

14 MS. METZINGER: Note the
15 objection again.

16 THE WITNESS: I'm not
17 comfortable answering that question
18 because you're creating a hypothetical
19 that doesn't exist. So if you'd like
20 to ask that question in another way,
21 you know, that -- that isn't quite so
22 hypothetical, I'd be happy to answer
23 it.

24 BY MR. WONE:

25 **Q. I'm going to refer to the claims**

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1 BY MR. WONE:

2 **Q. Paragraph 10 of your report --**

3 A. Yes.

4 **Q. -- MK1 --**

5 A. Yes.

6 **Q. -- you state in this -- in this**
7 **paragraph that you conducted a literature search**
8 **on the general topic of cognitive function as well**
9 **as the affects of apoeaquorin/Prevagen and vitamin**
10 **D3 on brain function and memory.**

11 **Do you see that?**

12 A. Yes, I do.

13 **Q. So the first search you -- if**
14 **I'm understanding right, was the first search you**
15 **did on the general topic of cognitive function?**

16 A. That's correct.

17 **Q. And how did you perform this**
18 **literature search?**

19 A. I used a database at the
20 University of Minnesota in which I put in keywords
21 related to cognitive function, dementia, mild
22 cognitive function, Alzheimer's disease, et
23 cetera, and looked at papers related to that in
24 order to provide a background and context for the
25 report.

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1 **Q. Was "memory" one of the search**
2 **terms you used?**

3 A. Yes.

4 **Q. Do you recall the name of the**
5 **database?**

6 A. The database I usually use is
7 Ovid, O-V-I-D. Very similar to PubMed.

8 **Q. And did anyone assist you with**
9 **your literature search?**

10 A. No.

11 **Q. And did you review all of the**
12 **results from your search?**

13 A. Yes, I did. I reviewed the
14 relevant results, right? So I might have gotten
15 hundreds of papers, and I reviewed the ones that
16 were the most relevant to what I was writing.

17 **Q. And did your search terms**
18 **include cognitive decline?**

19 A. I don't recall, but I think
20 probably I did, cognitive function, memory,
21 dementia. I may have had cognitive decline in
22 there, but it would have been picked up by the
23 other words.

24 **Q. And your second search was on**
25 **the effects of apoeaquorin/Prevagen?**

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1 A. Yes.
2 **Q. Okay. And how did you conduct**
3 **this literature search?**

4 A. Using the term "apoeaquorin,"
5 seeing -- seeing what else is out there in the
6 literature.

7 **Q. And did you use the same -- the**
8 **same database, Ovid?**

9 A. Yes.

10 **Q. Were there any other search**
11 **terms besides apoeaquorin?**

12 A. You know, I -- I don't have a
13 record in front of me of what search terms I used,
14 but I probably used apoeaquorin, brain, memory,
15 cognitive function, et cetera.

16 **Q. And did anyone assist you with**
17 **this literature search?**

18 A. No.

19 **Q. And did you review all of the**
20 **articles that you believed to be relevant?**

21 A. Yes.

22 **Q. And how about your search for**
23 **vitamin D? What search term did you use for that?**

24 A. Vitamin D and then various forms
25 of vitamin D. I would have put in there brain,

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1 memory, cognitive function, Alzheimer's, dementia.
2 Those kinds of terms would have been in there.

3 **Q. And it was also done -- the**
4 **vitamin D search was also done with the same**
5 **database, Ovid?**

6 A. Yes.

7 **Q. And did anyone assist you with**
8 **the vitamin D --**

9 A. No.

10 **Q. -- literature search?**

11 A. Nobody assisted me, no.

12 **Q. And did you review all of the**
13 **results from the vitamin D -- vitamin D literature**
14 **search that you believed to be relevant?**

15 A. Yes.

16 **Q. And do you know whether the**
17 **vitamin D literature search included cognitive**
18 **decline?**

19 A. It probably did, but I'm sure
20 that I used "mild cognitive impairment" as a
21 search term and "cognitive function" and "memory."
22 Those would have all picked up a paper on
23 cognitive decline.

24 **Q. You previously stated that you**
25 **don't consider yourself to be an expert in**

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1 **cognitive function. How do you know that the**
2 **studies you found in your literature search**
3 **represent the current view among experts in**
4 **cognitive function?**

5 MS. METZINGER: Objection to
6 form.

7 THE WITNESS: The way that I
8 know is that I'm a very, very
9 well-trained, experienced scientist,
10 and I'm able to evaluate data outside
11 of my area of expertise. I often have
12 to do this for grant applications, for
13 writing up of publications, et cetera.
14 I never have the luxury of just staying
15 within a very narrow area.

16 And so I explained before that
17 one of the things that I have taught in
18 my career is I've taught students how
19 to interpret data, how to interpret
20 papers. They aren't necessarily
21 published in the exact area of
22 expertise of the person who is reading
23 them. So a person who is experienced
24 at clinical trials, for example, has to
25 be able to interpret and understand

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1 animal studies and in vitro studies
2 even though that may not be where they
3 put most of their time and energy in
4 their own work. It is basic
5 understanding of science.

6 I also understand how to
7 evaluate the quality of journals, the
8 quality of authors of journals, and the
9 quality of -- of papers from the study
10 design, et cetera.

11 So I believe that I am very
12 qualified to evaluate the current
13 understanding about cognitive function
14 despite the fact that I don't have a
15 Ph.D. in a related science.

16 BY MR. WONE:

17 **Q. Did anyone assist you in**
18 **analyzing the results of your literature search?**

19 A. No.

20 **Q. If you could turn to page 37 of**
21 **your expert report which we marked as Exhibit MK1,**
22 **please. And when I say "page 37," I'm referring**
23 **to the pages that are printed at the bottom of the**
24 **document, not the page number in the -- in the**
25 **AgileLaw viewer.**

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1 A. Okay. Yes.

2 **Q. And is page 37 the first page of**
3 **your bibliography of your report?**

4 A. It is, yes.

5 **Q. Does this bibliography contain**
6 **sources that you found through your literature**
7 **search?**

8 A. Yes, it does.

9 **Q. Aside from documents related to**
10 **the Madison Memory Study, did you include any**
11 **other documents on your -- in your bibliography**
12 **that did not come from your literature search?**

13 A. I included some of my own
14 publications as references to comments that I made
15 about my experience in my introduction to my -- in
16 my introductory paragraphs.

17 **Q. Okay. Anything else?**

18 A. I don't believe so. Well, I may
19 have -- no, I believe that this is all from my
20 literature search. I think that I may have
21 been -- I may have been provided with some
22 unpublished papers by the attorneys representing
23 the defendant, but I don't recall if I referenced
24 them in the bibliography.

25 **Q. Did you rely on those**

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1 **unpublished papers as the basis for any of the**
2 **opinions in your report?**

3 A. The only unpublished paper that
4 I relied on was the reanalysis of the Madison
5 Memory Study data because the publication
6 evidently had some errors in the data analysis,
7 and so it was redone. And there was a subsequent
8 paper written which I did rely on because I wanted
9 to use the most current, accurate results.

10 **Q. Okay. And do you recall what**
11 **the errors were in the original publication?**

12 A. You know, I don't recall. There
13 were some statistical errors, I believe, and so I
14 didn't really go into great detail with the
15 attorneys about exactly what they were, but that
16 they -- but that I -- I did trust that when they
17 gave me the reanalyzed data, that that was
18 accurate.

19 **Q. So the opinions about the**
20 **Madison Memory Study in your report are based on**
21 **the Lerner reanalysis?**

22 A. Yes.

23 **Q. And to clarify, I don't know if**
24 **we covered it, when I said "Lerner," do you know**
25 **who that is?**

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1 A. I believe it's Kenneth Lerner,
2 the author of the papers, yes.

3 **Q. Okay.**

4 A. I know the name.

5 **Q. Okay. And he was the -- he was**
6 **the principal investigator for the reanalysis,**
7 **correct?**

8 A. Yes.

9 MS. METZINGER: Objection to
10 form.

11 BY MR. WONE:

12 **Q. Okay. If we could turn to**
13 **section 4 of your report, please, Exhibit MK1.**

14 A. What page would that be?

15 **Q. If you'll give me second, I will**
16 **let you know.**

17 **I believe it starts on page 4 of**
18 **your report.**

19 A. Okay. I see it.

20 **Q. Section 4 titled "Cognitive**
21 **Function and Its Measurement"?**

22 A. Yes.

23 **Q. Are the opinions expressed in**
24 **this section based on the results of your**
25 **literature search?**

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1 A. Yes.
 2 **Q. Are they based on any other**
 3 **experiences you've had in your career?**
 4 A. No. They're based on the
 5 literature search.
 6 **Q. And that's all on Section 4,**
 7 **correct?**
 8 A. Excuse me? Can you repeat that?
 9 **Q. The -- all -- when you said it's**
 10 **based on your literature search, you're referring**
 11 **to all of Section 4, correct?**
 12 A. Yes. Let me look at the...
 13 Yes.
 14 **Q. Okay. How about Section 5 of**
 15 **your report? It's on page 6. Is Section 5 also**
 16 **based solely on your literature search?**
 17 A. Yes, it is.
 18 **Q. In paragraph 28 of Exhibit MK1,**
 19 **also on page 6, do you see a mention of the**
 20 **Cogstate?**
 21 A. Yes.
 22 **Q. And what is your understanding**
 23 **of what Cogstate is?**
 24 A. Cogstate is a group of tests
 25 that test various aspects of cognitive function.

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1 And my understanding is that it's been validated
 2 and that it is listed in the NIH database of
 3 acceptable cognitive testing techniques.
 4 **Q. Have you ever used the Cogstate**
 5 **in any of your research?**
 6 A. No, I have not.
 7 **Q. Have you ever reviewed any**
 8 **journal articles -- strike that.**
 9 **Aside from this case, have you**
 10 **ever reviewed any journal articles that used the**
 11 **Cogstate?**
 12 A. Not in great detail. I did -- I
 13 remember looking at the literature to get a feel
 14 for when Cogstate has been used in other
 15 situations to make sure that I was confident that
 16 this is something that's been used in other -- in
 17 other published papers, and I did find that it had
 18 been used. So that was not something that I --
 19 that I cited in the -- in the report, but I
 20 remember that I did look into that.
 21 **Q. Okay. So did you also do a**
 22 **literature search on Cogstate?**
 23 A. I believe that I did, yes, for
 24 just for that purpose. It was really just to get
 25 a feel for the -- whether or not it had been used

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1 in other situations. I wanted to make sure of
 2 that.
 3 **Q. Okay. And did anyone assist you**
 4 **in the literature search regarding Cogstate?**
 5 A. No.
 6 **Q. If you could go down to**
 7 **paragraph 30 of your expert report.**
 8 A. Yes.
 9 **Q. The first paragraph of**
 10 **Section 6.**
 11 A. Yes.
 12 **Q. And do you see the first**
 13 **sentence were you're just starting with "both in**
 14 **vitro"?**
 15 A. Yes, I see that sentence.
 16 **Q. And so in reviewing the evidence**
 17 **in this case, you reviewed in vitro studies**
 18 **related -- involving apoeaquorin, correct?**
 19 A. Yes.
 20 **Q. And would any of the in vitro**
 21 **studies that you reviewed show that Prevagen**
 22 **improves memory in humans?**
 23 A. No, there would not be that
 24 direct connection. What the in vitro studies show
 25 was that apoeaquorin is neuro protective in a --

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1 in a situation in which the tissue has been
 2 removed. So it's not in a living human. It's in
 3 tissue in a cell culture model.
 4 **Q. And do you know whether the --**
 5 **sorry. Strike that.**
 6 **The tissue that was used in the**
 7 **in vitro studies was not human tissue, correct?**
 8 A. I think that it -- that is
 9 correct, but I'd have to see the paper because I
 10 have -- you know, I have 150 or 160 references
 11 here, so I'd have to -- if you want to show me the
 12 paper, I can look at it. But my recollection is
 13 that it was not human brain tissue.
 14 **Q. Okay.**
 15 A. But I'm not certain of that.
 16 **Q. Okay. I'm showing you what's**
 17 **been marked as Exhibit MK2.**
 18 **(Marked Exhibit MK2.)**
 19 BY MR. WONE:
 20 **Q. Do you see that, Dr. Kurzer?**
 21 A. Okay. I'm sorry. MK2. Yes.
 22 **Q. Is that the -- is that the**
 23 **research article you were citing to when you**
 24 **discussed in vitro studies?**
 25 A. Yes, it is.

<p style="text-align: right;">101</p> <p>1 Q. And did the research in 2 Exhibit MK2 involve human cells? 3 A. No. It was a rat brain slice 4 preparation. 5 Q. And do you agree that the 6 effects seen in the study in a rat brain cell may 7 not be the same in a human cell? 8 MS. METZINGER: Objection to 9 form. 10 THE WITNESS: I would say that 11 the rat results may be the same in a 12 human or may not be. We don't know. 13 BY MR. WONE: 14 Q. Okay. Going back to -- if you 15 could go back to Exhibit MK1. 16 A. Yes. 17 Q. Paragraph 30 again. 18 A. Okay. 19 Q. Do you see in that paragraph you 20 mention animal studies? 21 A. Yes. 22 Q. Do you agree that the animal 23 studies cited in paragraph 30 do not show that 24 Prevagen improves memory in humans? 25 MS. METZINGER: Objection to</p>	<p style="text-align: right;">103</p> <p>1 data are very, very strongly suggestive 2 because the model is so close to the 3 human brain. 4 BY MR. WONE: 5 Q. What do you mean when you say 6 "strongly suggestive"? 7 A. That's a very -- it's -- that's 8 kind of a subjective comment. What I mean is that 9 I would expect that these results would be 10 confirmed in human studies. I would expect that 11 to be the case. In the case of rat studies, in my 12 opinion, it could go either way. But in this 13 situation, because of these results and because of 14 the similarity of brain function and structure 15 between canines and humans, I would expect that 16 the same thing would occur in humans. 17 Q. Do you agree that humans are not 18 biologically identical to canines? 19 MS. METZINGER: Objection to 20 form. 21 THE WITNESS: I do agree that 22 humans are not biologically identical 23 to canines. I also agree that humans 24 are not biologically identical to each 25 other. There's a certain amount of</p>
<p style="text-align: right;">102</p> <p>1 form. 2 THE WITNESS: I would -- I would 3 say that the animal -- the canine 4 studies prove that Prevagen exerts this 5 function in canines. And in this 6 situation, I would trust the data to 7 apply to humans quite a bit more than 8 with rats because canines are 9 considered an excellent model for human 10 brain function. 11 The structure of the brain in 12 canines is very similar. Canines 13 experience age-related cognitive 14 decline. Canines have a lot of human 15 behavioral characteristics. And, in 16 fact, human drugs are used in canines. 17 For example, antidepressants. Prozac 18 is used in canines successfully. 19 So canine -- the canines brain 20 is thought to be an excellent model for 21 the human brain. And so in this case, 22 although it is not -- you could not 23 conclude -- conclusively say that these 24 results show that the same thing would 25 occur in humans, I do believe that the</p>	<p style="text-align: right;">104</p> <p>1 variability even between humans. 2 But, yes, of course canines and 3 humans are not biologically identical, 4 but the genetic makeup, as I'm sure you 5 know, of -- of canines and humans are 6 large -- have an enormous amount of 7 overlap. 8 BY MR. WONE: 9 Q. And do you know whether we 10 would -- whether the effects seen in the Milgram 11 study would happen in humans over the same 12 duration and dose? 13 MS. METZINGER: Objection to 14 form. 15 THE WITNESS: Can you repeat 16 your question, please, Mr. Wone? 17 BY MR. WONE: 18 Q. Sure. 19 Do you know whether the effect 20 that was seen in the Milgram study would happen in 21 humans when you -- considering the same duration 22 and dose? 23 A. I do not know that for certain. 24 I would expect that to be the case, but I 25 certainly did not know that for certain because</p>

<p style="text-align: right;">105</p> <p>1 the study was done in canines.</p> <p>2 Q. I've marked and introduced</p> <p>3 what's been labeled as Exhibit MK3.</p> <p>4 (Marked Exhibit MK3.)</p> <p>5 BY MR. WONE:</p> <p>6 Q. Do you see that, Doctor?</p> <p>7 A. I do.</p> <p>8 Q. And is this one of the documents</p> <p>9 you analyzed for your report?</p> <p>10 A. Yes, it is.</p> <p>11 Q. And is this the Lerner</p> <p>12 reanalysis that we discussed earlier?</p> <p>13 A. Yes, it is.</p> <p>14 Q. I've marked another document</p> <p>15 which has been labeled as Exhibit MK4.</p> <p>16 (Marked Exhibit MK4.)</p> <p>17 BY MR. WONE:</p> <p>18 Q. Do you see that, Doctor?</p> <p>19 A. Yes, I do.</p> <p>20 Q. And is this another document</p> <p>21 that you reviewed in connection with the -- in</p> <p>22 connection with your report?</p> <p>23 A. Yes, it is.</p> <p>24 Q. And is Exhibit 4, MK4, the</p> <p>25 analysis that you said had errors?</p>	<p style="text-align: right;">107</p> <p>1 Q. -- MK4?</p> <p>2 A. That's correct.</p> <p>3 Q. You mentioned that the</p> <p>4 reanalysis was done by Georgetown Economic</p> <p>5 Services in paragraph 33. Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. And were you involved in any way</p> <p>8 in this reanalysis?</p> <p>9 A. I was not.</p> <p>10 Q. Have you ever had any</p> <p>11 interactions with anyone affiliated with</p> <p>12 Georgetown Economic Services?</p> <p>13 MS. METZINGER: Objection.</p> <p>14 Dr. Kurzer, again, I would</p> <p>15 caution you not to divulge the</p> <p>16 substance of any communications that</p> <p>17 you may have had with Georgetown</p> <p>18 Economic Services to the extent that</p> <p>19 counsel may have been involved in those</p> <p>20 communications.</p> <p>21 THE WITNESS: Okay.</p> <p>22 Best that I don't answer the</p> <p>23 question, I guess.</p> <p>24 BY MR. WONE:</p> <p>25 Q. Well, I'm not asking for the</p>
<p style="text-align: right;">106</p> <p>1 A. Yes, it is. I was told that.</p> <p>2 Q. You were told that by the -- by</p> <p>3 the defendants' attorneys?</p> <p>4 A. Yes.</p> <p>5 MS. METZINGER: Objection to</p> <p>6 form.</p> <p>7 And, Dr. Kurzer, I would just</p> <p>8 caution you not to divulge the</p> <p>9 substance of any communications that</p> <p>10 you've had with counsel.</p> <p>11 THE WITNESS: Thank you.</p> <p>12 BY MR. WONE:</p> <p>13 Q. If you would go to paragraph 33</p> <p>14 of your report, please, Exhibit MK1.</p> <p>15 A. Yes.</p> <p>16 Q. In the first sentence, you</p> <p>17 wrote, "After initial publication in the Madison</p> <p>18 Memory Study results, it was discovered that</p> <p>19 transformation and dataset errors had been made in</p> <p>20 the data analyses."</p> <p>21 Do you see that, Doctor?</p> <p>22 A. Yes.</p> <p>23 Q. And that's your understanding</p> <p>24 of -- of the errors that were in Exhibit --</p> <p>25 A. Yes.</p>	<p style="text-align: right;">108</p> <p>1 substance of the communications. I'm just asking</p> <p>2 now whether you've had any interactions with</p> <p>3 anyone affiliated with Georgetown Economic</p> <p>4 Services.</p> <p>5 A. You know, actually, honestly, I</p> <p>6 don't recall. I may have, but I don't recall.</p> <p>7 Q. Have you ever had any</p> <p>8 interactions with someone named Howard Beales in</p> <p>9 connection with your work in this case?</p> <p>10 A. What's the name?</p> <p>11 Q. Howard Beales.</p> <p>12 A. Howard Bealed. I don't believe</p> <p>13 so.</p> <p>14 Q. Beales.</p> <p>15 A. Spelled, please.</p> <p>16 Q. B-E-A-L-E-S.</p> <p>17 A. Beales. I don't believe so.</p> <p>18 Q. And were you involved in any way</p> <p>19 with the Madison Memory Study?</p> <p>20 A. I was not.</p> <p>21 MS. METZINGER: Objection to</p> <p>22 form.</p> <p>23 BY MR. WONE:</p> <p>24 Q. Have you ever spoken with anyone</p> <p>25 who was involved with conducting the Madison</p>

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Memory Study?

A. I don't believe I have.

Q. Have you ever had any interactions with anyone involved in analyzing data from the Madison Memory Study?

MS. METZINGER: Objection to form.

And, again, Dr. Kurzer, I would just caution you not to divulge the substance of any communications that you have had with counsel. If you can answer Mr. Wone's question without doing so, you're free to answer the question.

THE WITNESS: Okay.

Mr. Wone, can you repeat the question, please?

BY MR. WONE:

Q. Sure.

Have you ever had any interactions with anyone who was involved in analyzing the Madison Memory Study data?

A. I don't believe so.

Q. Okay. I'm introducing what has been marked as Exhibit MK5.

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(Marked Exhibit MK5.)

THE WITNESS: Yes.

BY MR. WONE:

Q. Do you see that, Dr. Kurzer?

A. I do.

Q. And have you seen this document before?

A. I have.

Q. And could you describe what Exhibit MK5 is?

A. MK5 is a protocol, I believe, for the Madison Memory Study.

Q. And who is listed as the principal investigator for the Madison Memory Study?

A. KC Lerner is listed.

Q. And based on this protocol, what was the Madison Memory Study's population?

MS. METZINGER: Objection to form.

THE WITNESS: The study population on this protocol is adults between the ages of 40 and 95, 100 adults between the ages of 40 and 95.

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BY MR. WONE:

Q. I'm sorry. I missed it. What was the last part of your response, Dr. Kurzer?

A. 100 adults between the ages of 40 and 95.

Q. Thank you.

When the Madison Memory Study was conducted, do you know how many participants were in the study?

A. I believe they recruited over 200 people.

Q. In your experience, is it common to recruit more than double the population for a given study?

MS. METZINGER: Objection to form.

THE WITNESS: I don't believe it's common, but I believe that it does happen. There are many reasons why investigators might want to do so.

BY MR. WONE:

Q. And do you know why the -- why the investigators in the Madison Memory Study recruited over 200 participants?

A. I don't know their reason.

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Q.

MS. METZINGER: Objection to form.

THE WITNESS:

BY MR. WONE:

Q. And what did -- sorry. Strike that.

A.

Q.

specific Cogstate measures to be used?

A. No, it doesn't.

Q. In your experience, is it good methodological practice to not identify the specific measures to be used in a study in the protocol?

MS. METZINGER: Objection to form.

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1 THE WITNESS: I don't think that
2 it's -- I can't really comment on that.
3 I think there were many reasons -- and
4 there are many situations in which
5 investigators will speak more generally
6 in a protocol rather than very
7 specifically.

8 So, for example, I could imagine
9 writing up a protocol in which I say
10 that I'm going to be measuring estrogen
11 metabolites without listing the exact
12 ones that I'm going to be measuring.
13 So I don't think it's -- it is good
14 practice or bad practice. I think it
15 is practice that I've seen before.

16 BY MR. WONE:

17 **Q. In the protocols you worked on,**
18 **have you had protocols where you didn't list --**
19 **didn't identify the primary efficacy variables?**

20 MS. METZINGER: Objection to
21 form.

22 THE WITNESS: No, I would say
23 that I have identified the primary
24 efficacy variables, but there are
25 degrees of detail that I may or may not

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1 paper is describing the study design. They may or
2 may not go into great detail. Of course in the
3 results, they then will list exactly what they
4 were evaluating. But in the message section,
5 they -- there are variations in the amount of
6 detail that people go into.

7 **Q. Do you know whether the**
8 **investigators in the Madison Memory Study had any**
9 **space limitations in drafting their protocol?**

10 A. I do not know.

11 **Q. Do you know which Cogstate**
12 **measures were used in the Madison Memory Study?**

13 A. I -- I don't -- I know that
14 there were eight or nine different -- different
15 measures, and I'd have to look at the paper to be
16 able to name them all. But I -- you know, I did
17 look at them very closely.

18 **Q. So if you'd like to refer back**
19 **to Exhibit MK3.**

20 A. Okay.

21 **Q. Does Exhibit MK3 identify the**
22 **Cogstate measures that you believe --**

23 A. Yes.

24 **Q. -- were used in the Madison**
25 **Memory Study?**

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1 have gone into in describing them.
2 BY MR. WONE:

3 **Q. And is that because when you're**
4 **drafting your protocols you -- you always have**
5 **page limitations?**

6 A. It's page limitations. Also the
7 methodology that I'm using. I might not be
8 certain which of them I'm going to be able to
9 analyze, you know, chemically what's going to be
10 practical, et cetera. And so there are various
11 reasons why I might not go into as much detail.

12 And some protocols would -- you
13 know, in some situations if I'm writing a protocol
14 for an organization like NIH, they might have
15 certain requirements of their own regarding the
16 detail. But I wouldn't say that it is broadly
17 accepted that every protocol has to go into a
18 certain amount of detail. There's variability in
19 that, and that's accepted, widely accepted.

20 **Q. When you say "widely accepted,"**
21 **you mean -- what do you mean? By who?**

22 A. I mean, I see it all the time in
23 -- in scientific -- in grants that I've reviewed,
24 in -- in papers that are -- that are reporting on
25 protocols on study design where they -- the whole

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1 A. Yes, it does. In table 1, it
2 lists nine different tests that were used.

3 **Q. And do you know whether there**
4 **are any other Cogstate measures that were used in**
5 **the Madison Memory Study that are not included in**
6 **table 1?**

7 A. I don't recall.

8 **Q. In table 1 of Exhibit MK3,**
9 **there's two columns, correct?**

10 A. Yes.

11 **Q. One labeled "Task," the other**
12 **one labeled "Cognitive Domain Measured"?**

13 A. Yes.

14 **Q. Is it your understanding that**
15 **the column under Cognitive Domain Measured**
16 **identifies which domain corresponds to a specific**
17 **task?**

18 A. Yes, I -- that's my
19 understanding.

20 I also understand that there's
21 tremendous overlap among these, that they're not
22 entirely discrete. Discrete memory is not
23 entirely independent and separate from executive
24 function. Verbal learning obviously requires
25 memory. So there's tremendous overlap among

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1 these, but I do agree and understand that they are
2 thought to represent primarily these particular
3 cognitive domains.

4 **Q. And is it your understanding --**
5 **what is your understanding that they're not --**
6 **that the cognitive domains are not discrete based**
7 **on?**

8 MS. METZINGER: Objection to
9 form.

10 THE WITNESS: It's based on my
11 evaluation of the literature and
12 reading general papers that discuss
13 cognitive function and measurements of
14 cognitive function and what contributes
15 to memory and what factors contribute
16 to memory and what memory is important
17 for.

18 So in the background reading
19 that I -- that I did, which was
20 significant for this, it was very clear
21 that these are -- have enormous
22 overlap. Plus, there are a number
23 of -- of studies and there are a number
24 of publications that state very clearly
25 that these measures are not

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1 independent.

2 BY MR. WONE:

3 **Q. And you're referring back to**
4 **publications or information that you obtained from**
5 **your literature search that we --**

6 A. Yes.

7 **Q. -- discussed earlier?**

8 A. Yes.

9 **Q. If we could go back to**
10 **Exhibit MK5.**

11 A. Okay.

12 **Q. What is the investigational**
13 **product identified in Exhibit MK5?**

14 A. Well, the -- in the title, it
15 states Prevagen apocaequorin dietary supplement.

16 **Q. So Prevagen is the product being**
17 **studied in the Madison Memory Study?**

18 A. That's correct. Yes, here we
19 go. Prevagen 10 milligrams.

20 **Q. And did the protocol in**
21 **Exhibit MK5 discuss how the data from the study**
22 **would be analyzed?**

23 MS. METZINGER: Objection to
24 form.

25 THE WITNESS: There is a brief

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1 description of the statistical analysis
2 on page 5.

3 BY MR. WONE:

4 **Q. Did the protocol identify the**
5 **specific statistical test that would be used to**
6 **analyze the data?**

7 MS. METZINGER: Objection.

8 THE WITNESS: It did not.

9 BY MR. WONE:

10 **Q. Did the protocol in Exhibit MK5**
11 **identify how the data would be analyzed?**

12 MS. METZINGER: Objection to
13 form.

14 THE WITNESS: If you mean does
15 it describe the specific statistical
16 tests that will be used, it does not.

17 BY MR. WONE:

18 **Q. Did the protocol identify**
19 **whether the tests would be analyzed separately or**
20 **collectively?**

21 MS. METZINGER: Objection to
22 form.

23 THE WITNESS: I don't believe
24 that it does.
25

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1 BY MR. WONE:

2 **Q.** 

3
4
5
6 MS. METZINGER: Objection to
7 form.

8 THE WITNESS: 

9
10 BY MR. WONE:

11 **Q. Do you know whether subgroups**
12 **were used in the Madison Memory Study?**

13 MS. METZINGER: Objection to
14 form.

15 THE WITNESS: I don't believe
16 that subgroups were used in the sense
17 that they analyzed the group that they
18 were intending to analyze. They -- the
19 intent of the study was to look at
20 healthy people, and so they analyzed
21 the AD 0-2 group, which was a group
22 that I focused on, because that was the
23 intent of the study. So they
24 over-recruited. And in the
25 recruitment, they included additional

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1 people. But when they did the
2 statistical analysis, they did it on
3 the population which they were aiming
4 to study at the beginning of the study.
5 BY MR. WONE:
6 **Q. Were all of the participants in**
7 **the Madison Memory Study in the AD8 0-2 group?**
8 A. No, they were not.
9 **Q. And what is -- what do you mean**
10 **when you say "AD8"?**
11 A. That's the -- the -- the
12 Alzheimer's disease screening form which has eight
13 questions related to changes in memory over time.
14 And if there are eight questions and if someone
15 says yes to all eight saying that they've had
16 changes and problems with all eight areas of
17 memory, then that would be viewed -- an 8 or 7
18 would be viewed as, you know, severe dementia.
19 0-2 is viewed where you just
20 have nothing you answer yes to or maybe you answer
21 yes to one or two of the questions. That would be
22 considered normal cognitive decline with aging or
23 possibly mild cognitive impairment. But basically
24 healthy people would be in the -- in my opinion,
25 healthy people would be in the 0-2 on the AD8

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1 form.
2 **Q. And prior to reviewing the**
3 **Madison Memory Study, were you familiar with the**
4 **AD8 tool?**
5 MS. METZINGER: Objection to
6 form.
7 THE WITNESS: I was familiar
8 with it, yes.
9 BY MR. WONE:
10 **Q. Have you ever used the AD8 in**
11 **your own research?**
12 A. I have not.
13 **Q. How did you become familiar with**
14 **the AD8 tool?**
15 A. My mother had dementia, and so
16 I -- I learned about it in the context of her
17 clinical experience, just from my family personal
18 experience.
19 **Q. Okay. Have you ever used the**
20 **AD8 tool in your professional work?**
21 A. I have not.
22 **Q. Is the AD8 tool mentioned in the**
23 **protocol that's in Exhibit MK5?**
24 A. It's not.
25 **Q.**

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1 [REDACTED]
2 [REDACTED]
3 A. [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED]
9 [REDACTED]
10 [REDACTED]
11 Q. [REDACTED]
12 [REDACTED]
13 A. [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 **Q. And would somebody who scored a**
18 **3 on the AD8 tool have significant neurological**
19 **disease?**
20 MS. METZINGER: Objection to
21 form.
22 THE WITNESS: My understanding
23 is that the -- at the level of AD8 3,
24 it is the beginning of more severe
25 cognitive dysfunction. Therefore, a

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1 cutoff of 2 is the appropriate place to
2 differentiate healthy people from
3 people who are beginning to develop
4 more serious dementia and cognitive
5 dysfunction.
6 BY MR. WONE:
7 **Q. So if somebody is beginning to**
8 **develop, does that mean they have a history of**
9 **significant neurological disease?**
10 MS. METZINGER: Objection to
11 form.
12 THE WITNESS: Yes, in the sense
13 that patient has a history, could be
14 synonymous with patient has existing
15 significant neurological disease.
16 So the history implies long in
17 the past, but my interpretation of this
18 is patient has a history of significant
19 neurological disease means we don't
20 want to recruit people with significant
21 neurological disease. And history is
22 used often -- it's a medical term, and
23 it's often used in these protocols.
24 But what we mean is existing.
25

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1 BY MR. WONE:

2 **Q. And what is your basis for**
3 **the -- your interpretation of what significant**
4 **neurological disease means?**

5 A. Can you rephrase that question,
6 please, Mr. Wone?

7 **Q. Sure.**

8 **How do you know -- so you've**
9 **given me your interpretation of significant**
10 **neurological disease and what you think it means,**
11 **correct?**

12 MS. METZINGER: Objection.

13 THE WITNESS: I don't have --

14 I'm not exactly sure what you're
15 asking. I understand that -- that AD8
16 0-2 is the categorization of people who
17 are generally healthy and that once you
18 get to 3 and above, you're moving into
19 the territory of people who have more
20 than normal aging cognitive decline and
21 more than mild cognitive decline. And
22 this I know from the reading that I've
23 done from the literature review.

24 BY MR. WONE:

25 **Q. And do you know whether the**

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1 **investigators of the Madison Memory Study had the**
2 **same understanding of what significant**
3 **neurological disease means in Exhibit 5, MK5?**

4 A. I assume yes. I assume that
5 they had the same understanding. It seems to me
6 to be fairly obvious.

7 **Q. Did the protocol mention in**
8 **Exhibit MK5 -- sorry, strike that.**

9 **Did the protocol in Exhibit MK5**
10 **mention any interim analysis?**

11 A. I don't believe that it did, no.

12 **Q. And in your experiences**
13 **conducting RCTs, is an interim analysis something**
14 **you would include in a protocol?**

15 MS. METZINGER: Objection to
16 form.

17 THE WITNESS: Not necessarily,
18 no. In fact -- in fact, in the green
19 tea trial that I did, the clinical
20 trial with a thousand participants who
21 consumed green tea for -- for a year,
22 green tea supplement for a year, we did
23 not state in the protocol that we were
24 going to do an interim analysis, but we
25 decided to, to do an interim analysis.

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1 And in our case, it was to look for
2 adverse events, to make sure that there
3 weren't any adverse events. And so we
4 did do an interim analysis even though
5 it was not stated in the protocol. And
6 that was approved by the data safety
7 and monitoring board and it was
8 approved by NIH. It was not a problem
9 that it was not in the original
10 protocol.

11 BY MR. WONE:

12 **Q. And so you reported the interim**
13 **analysis to NIH when you --**

14 A. Yes.

15 **Q. Correct?**

16 A. Yes. Yes.

17 **Q. Do you know whether any interim**
18 **analysis was done in the Madison Memory Study?**

19 A. I believe that they did do some
20 interim analyses after -- possibly after 30 days
21 and 60 days in addition to the final reported
22 analysis on day 90.

23 **Q. And do you know whether those**
24 **interim analyses were related to safety or looking**
25 **for adverse events?**

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1 A. I don't believe so. I believe
2 that they were looking for efficacy. And in many
3 clinical trials, that -- it's -- it's -- it's not
4 uncommon to do an interim analysis to look at
5 efficacy because in the case of very important
6 drug studies, for example, if something is found
7 to be efficacious partway through the study, they
8 might be so -- feel that this is such an important
9 finding that they feel like the study should be
10 stopped and the drug should be, you know, moved to
11 approval. So it's not unheard of to do interim
12 analyses for efficacy as well as for adverse
13 events.

14 **Q. And in those situations when the**
15 **interim analysis is performed, would it be later**
16 **discussed in the study report?**

17 MS. METZINGER: Objection to
18 form.

19 THE WITNESS: Not necessarily.
20 In fact, we published -- for the green
21 tea trial, we published at least two
22 papers on adverse events, and I don't
23 believe that we talked about the
24 interim analysis in either one because
25 it was more of -- you know, it was not

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1 something that we felt was a primary
2 endpoint, and so it was not in the
3 final publication.

4 BY MR. WONE:

5 **Q. Could you explain that further?**
6 **What was not considered the primary endpoint?**

7 A. The interim -- the results of
8 the interim report. So in the case of the green
9 tea trial where we did an interim analysis of
10 adverse events, we didn't feel that it was
11 necessary to put that interim analysis in the
12 final report because what was of most interest to
13 people reading the report are the final results.

14 **Q. And did you find any adverse**
15 **events in that green tea trial?**

16 A. We found minimal adverse events.
17 We found some, but not enough to -- to be viewed
18 as a problem by FDA or NIH.

19 **Q. Would you describe -- would you**
20 **agree that the results of the Madison Memory Study**
21 **were related to cognitive function?**

22 A. Yes.

23 **Q. And would you agree that those**
24 **results were the primary focus of the Madison**
25 **Memory Study?**

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1 A. Yes.

2 **Q. And is it your -- is it your**
3 **understanding that the interim analysis looked at**
4 **efficacy related to cognitive function?**

5 MS. METZINGER: Objection to
6 form.

7 THE WITNESS: I believe that
8 they did. But I think that the primary
9 interest was what happened at the end
10 of the study. So in the report, the
11 focus was on the end of the study. And
12 I have done studies where I analyzed
13 endpoints during the study, but the
14 report focused on the end-of-study data
15 because that's what is of most
16 interest. And when you write a
17 publication, you don't want to flood
18 the reader with so much stuff that it's
19 going to be difficult for them to get
20 the main gist of what you're trying to
21 say.

22 So there's a balance between
23 being -- being honest and having
24 integrity and presenting what you found
25 and at the same time not putting so

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1 much stuff into the -- into the -- into
2 the report that it's really hard to
3 read and difficult to -- for the reader
4 to understand what the most important
5 thing is.

6 BY MR. WONE:

7 **Q. But you agree that the Madison**
8 **Memory Study's interim analysis related to the**
9 **primary interest of the study?**

10 A. Yes. Oh, excuse me. I'm sorry.
11 Can you repeat that question? I'm not sure I
12 heard it correctly.

13 MR. WONE: Could the court
14 reporter please read that back.
15 (Reporter read back requested
16 material.)

17 THE WITNESS: I -- I need to --
18 to change my response on that. I think
19 that it related to it in the sense that
20 it was focused on the same endpoints
21 of -- that -- that reflect cognitive
22 function. But I don't think that the
23 30-day or 60-day endpoints were the
24 primary interest for the reader. I
25 think that the 90-day end of study

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1 endpoint would be the primary interest.

2 BY MR. WONE:

3 **Q. Did the protocol mentioned in**
4 **Exhibit MK5 state whether the Madison Memory Study**
5 **was blinded?**

6 A. Yes, it said it was blinded.

7 **Q. And did the protocol in**
8 **Exhibit MK5 describe how the blinding was done?**

9 A. No, it did not describe it. And
10 I would be surprised if it did. It's -- it's not
11 common for researchers to put in the protocol
12 exactly what the mechanism of blinding is going to
13 be. You know, there are many, many methods of
14 blinding, and I'm not familiar -- I think that
15 it's -- it's more detail than is of interest to
16 most either reviewers or -- or, you know, grant
17 reviewers, manuscript reviewers, et cetera. It's
18 not usually put in. That's -- that's -- that's
19 drilling down very, very into the weeds, in my
20 opinion.

21 **Q. Okay. Going back to the AD8 for**
22 **a moment, do you know how the AD8 was administered**
23 **in the Madison Memory Study?**

24 A. The AD8 was administered to the
25 prospective participants.

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1 **Q. And did the participants**
2 **complete the AD8 tool themselves?**

3 A. I believe that they did, yes.

4 **Q. Do you agree that it's**
5 **preferable to have the AD8 administered with an**
6 **informant?**

7 MS. METZINGER: Objection --

8 THE WITNESS: Yes.

9 MS. METZINGER: -- to form.

10 THE WITNESS: Yes. I -- I -- I

11 know that I have read that is it

12 preferable to have it administered by

13 an informant, but I have also read that

14 in instances where that is not

15 practical or possible, it is acceptable

16 to have it administered directly to the

17 participant.

18 BY MR. WONE:

19 **Q. And do you know in the case of**
20 **the Madison Memory Study whether it was possible**
21 **to have the AD8 administered through an informant?**

22 A. I do not know that.

23 **Q. Do you know whether it was**
24 **practical in the Madison Memory Study to have the**
25 **AD8 administered through an informant?**

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1 A. I do not.

2 **Q. Do you agree that the results of**
3 **the AD8 when administered directly to the**
4 **participant may not be as reliable versus when**
5 **it's administered through an informant?**

6 MS. METZINGER: Objection to
7 form.

8 THE WITNESS: I believe that the
9 reliability is thought to be best when
10 administered by an informant, but at
11 the same time it doesn't mean that it's
12 unreliable when administered to the
13 participant.

14 BY MR. WONE:

15 **Q. A few moments ago you mentioned**
16 **that the AD8 0-2 was the group of primary**
17 **interest, correct?**

18 A. Yes.

19 **Q. I wanted to ask, what was --**
20 **what was your basis of that understanding?**

21 A. The basis of that understanding
22 is my reading of the protocol which states that
23 they want healthy people and not people who
24 have -- who are exhibiting neurological symptoms
25 coupled with my understanding that interpreting

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1 the -- the AD8 -- interpretation of the AD8 is
2 such that the 0-2 group is what would be
3 considered the healthy population without
4 significant neurological changes.

5 **Q. What would be the difference**
6 **between the 0-1 group versus the 0-2 group in**
7 **terms of neurological condition?**

8 MS. METZINGER: Objection to
9 form.

10 THE WITNESS: My understanding
11 is that the 0-1 group would be viewed
12 as having no cognitive dysfunction, and
13 the 0-2 group might include some people
14 with some very mild cognitive
15 dysfunction.

16 BY MR. WONE:

17 **Q. Did the protocol in Exhibit MK5**
18 **discuss randomization?**

19 A. I believe that they say that the
20 subjects will be randomized, but they don't
21 describe in detail how that will be. I'm glancing
22 through it right now, so -- to try to better
23 recall.

24 Yes, they do say that -- that it
25 is randomized. They say in the methodology that

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1 the participants will be randomized.

2 **Q. Did the protocol state how the**
3 **randomization would be done?**

4 A. The protocol did not state
5 exactly how the randomization would be done. And
6 this is extremely acceptable, in my opinion.
7 There are many ways to do randomization. It can
8 be done by computer. It can be done by a number
9 of different programs. You can Google
10 randomization and there are websites that will
11 help you randomize. You can pick names out of a
12 hat to randomize. There are lots of different
13 ways. And it would be very unusual for the
14 principal -- the -- the investigators to describe
15 exactly what their method of randomization is.
16 Usually saying "randomized" is good enough for us
17 when we're reading a protocol or a paper.

18 **Q. And did the -- did the protocol**
19 **in Exhibit MK5 discuss stratification of the**
20 **participants?**

21 A. No, they did not. But as I
22 said, I don't believe that the participants were
23 stratified in the sense that the group that they
24 analyzed, the 0-2 group, in my opinion, was the
25 group of interest from the start. So I don't

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1 think this is a stratification in the sense that
2 we were discussing before.

3 **Q. If the 0-2 group was the group**
4 **of interest, do you know where the Madison Memory**
5 **Study included participants outside of that group?**

6 MR. de LEEUW: Object to the
7 form.

8 THE WITNESS: I do not know
9 that. I do not know that. But there
10 are many possible reasons that would be
11 completely legitimate.

12 BY MR. WONE:

13 **Q. Does the protocol in Exhibit MK5**
14 **identify the ratio of participants in the**
15 **treatment versus placebo groups?**

16 A. No, they don't.

17 **Q. And do you know how the**
18 **participants with AD8 scores of 0, 1, and 2 were**
19 **distributed between the placebo and treatment**
20 **groups?**

21 A. I don't recall. I would have to
22 look at the paper. Ratio 3 to 2 is the -- is they
23 reported.

24 **Q. And do you know whether that 3**
25 **to 2 ratio was in place at each of the AD8 levels,**

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1 population.

2 BY MR. WONE:

3 **Q. If the treatment and placebo**
4 **groups are not following the 3 to 2 ratio at each**
5 **specific AD8 score, could that affect the study**
6 **results?**

7 MS. METZINGER: Objection to
8 form.

9 THE WITNESS: Can you rephrase
10 the question, please, Mr. Wone?

11 BY MR. WONE:

12 **Q. Sure.**

13 **So you testified you don't know**
14 **whether the 3 to 2 ratio was in place at each of**
15 **the specific AD8 0, 1, and 2 levels, correct?**

16 A. That's correct.

17 **Q. And would it affect -- could it**
18 **affect the results if there were different numbers**
19 **of participants at each of those levels between**
20 **the treatment of placebo groups that didn't follow**
21 **the 3 to 2 ratio?**

22 MS. METZINGER: Objection to
23 form.

24 THE WITNESS: In looking at
25 table number 2 in Exhibit -- in

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1 **so 3 to 2 ratio at AD8 0 and 3 to 2 ratio AD8 1**
2 **and a 3 to 2 ratio at AD8 2?**

3 MS. METZINGER: Objection to
4 form.

5 THE WITNESS: I do not know. I
6 don't think that they stated that. I'm
7 looking at the study design right now.
8 I don't believe they said any -- I
9 don't believe that they commented on
10 that.

11 BY MR. WONE:

12 **Q. And would you expect that the 3**
13 **to 2 ratio would be consistent across each of the**
14 **specific AD8 levels?**

15 MS. METZINGER: Objection to
16 form.

17 THE WITNESS: I would not
18 require that or expect that. I think
19 it would be good if the ratio was met
20 what they were -- what they were
21 looking for within the group of
22 interest, which is the 0-2. So that's
23 where I would want this 3 to 2 applied
24 within the 0 to 2 group. I wouldn't be
25 as concerned with the rest of the

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1 document MK3, you can see that in the
2 AD8 0-2 group that ratio is followed.
3 And that is the place where I would
4 want it to be followed because I
5 believe that that is the main outcome
6 of interest. The main outcome of
7 interest is the AD8 0-2. So that's
8 where that ratio would need to be
9 applied.

10 BY MR. WONE:

11 **Q. But it's your understanding that**
12 **there could be different numbers of AD8 1 in the**
13 **treatment and placebo groups that are not**
14 **following the 3 to 2 ratio at that specific score,**
15 **correct?**

16 MS. METZINGER: Objection to
17 form.

18 THE WITNESS: I'd have to take
19 out my calculator and do a calculation,
20 but the 0-1 group is listed right next
21 to it. And there are 24 in the placebo
22 and 37 in the apoeaquorin, so the ratio
23 may be slightly different in the 0-1
24 rather than the 0-2. But you can see
25 that it's very -- there are more in the

<p style="text-align: right;">141</p> <p>1 apoeaquorin, significantly more.</p> <p>2 BY MR. WONE:</p> <p>3 Q. No. I was asking about just AD8</p> <p>4 1, for example. In the 0-2 group, do you know</p> <p>5 whether the 3 to 2 ratio was followed for</p> <p>6 participants with AD8 1?</p> <p>7 MS. METZINGER: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: Tell me if I'm --</p> <p>10 if I'm misunderstanding you, but if you</p> <p>11 look at table 2 on page 5, the</p> <p>12 right-hand side has AD8 0-1.</p> <p>13 BY MR. WONE:</p> <p>14 Q. So I'm not including the 0. I'm</p> <p>15 just asking --</p> <p>16 A. I see. I see.</p> <p>17 Q. -- specific level.</p> <p>18 A. I see. 0 -- rather -- just --</p> <p>19 just the level 1.</p> <p>20 Q. Yes.</p> <p>21 A. From the paper -- from the</p> <p>22 paper, it is not apparent what the ratio was for</p> <p>23 each individual level of 0, 1, 2, 3, 4.</p> <p>24 Q. Okay. And could it affect the</p> <p>25 results if the ratio was not the same at each</p>	<p style="text-align: right;">143</p> <p>1 using the word "correlation." But I</p> <p>2 think maybe you're asking something</p> <p>3 that's a little bit more general than a</p> <p>4 statistical question which is could the</p> <p>5 baseline value influence how they</p> <p>6 respond later. Is that what you're</p> <p>7 asking?</p> <p>8 BY MR. WONE:</p> <p>9 Q. I'm asking whether -- would you</p> <p>10 expect -- here, I'll rephrase. Hold on a second.</p> <p>11 Would you expect the people who</p> <p>12 did better in the AD8 -- well, I should qualify.</p> <p>13 Would you expect the people who</p> <p>14 are lower scores in the AD8 measure to do better</p> <p>15 in Cogstate tests at baseline?</p> <p>16 MS. METZINGER: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: I think that</p> <p>19 that's possible. They probably would.</p> <p>20 And that's why it was important for</p> <p>21 them to compare baseline values on</p> <p>22 Cogstate between the placebo and the</p> <p>23 treatment group. And you can see on</p> <p>24 table 2 when you look at the AD8 0-2</p> <p>25 group, there is no difference at</p>
<p style="text-align: right;">142</p> <p>1 specific level within the AD8 0-2 group?</p> <p>2 MS. METZINGER: Objection to</p> <p>3 form.</p> <p>4 THE WITNESS: I don't know if it</p> <p>5 would affect the results. I really</p> <p>6 can't comment on that. I think it's</p> <p>7 possible that it would. It's possible</p> <p>8 that it wouldn't. And, you know, there</p> <p>9 were many other things that could</p> <p>10 affect the results too. So personally</p> <p>11 I'm not concerned about that.</p> <p>12 BY MR. WONE:</p> <p>13 Q. Is it your understanding that</p> <p>14 Cogstate measures when given at baseline indicated</p> <p>15 the participant's level of cognitive function?</p> <p>16 A. Yes.</p> <p>17 Q. And would you expect in the</p> <p>18 Madison Memory Study for the participants AD8</p> <p>19 scores to be correlated with their performance on</p> <p>20 the Cogstate measures at baseline?</p> <p>21 MS. METZINGER: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: Maybe you can</p> <p>24 clarify that question for me because</p> <p>25 you're asking a statistical question by</p>	<p style="text-align: right;">144</p> <p>1 baseline in -- in the scores that they</p> <p>2 have on the tests. So that is</p> <p>3 important.</p> <p>4 And I also believe that they</p> <p>5 took baseline into account in their</p> <p>6 data analysis so that they -- they used</p> <p>7 baseline as a co-variable so that that</p> <p>8 was taken into account because that is</p> <p>9 important.</p> <p>10 BY MR. WONE:</p> <p>11 Q. Did you look at any data to see</p> <p>12 how participants in the Madison Memory Study did</p> <p>13 on the AD8 scores versus how they did at Cogstate</p> <p>14 tests at baseline?</p> <p>15 MS. METZINGER: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: I don't recall</p> <p>18 that they did that comparison or that</p> <p>19 they reported it.</p> <p>20 BY MR. WONE:</p> <p>21 Q. And it wasn't something that you</p> <p>22 looked at?</p> <p>23 A. No.</p> <p>24 Q. Do you know when the Madison</p> <p>25 Memory Study began?</p>

<p style="text-align: right;">145</p> <p>1 A. I believe that it began in 2009.</p> <p>2 Q. And do you know when it ended?</p> <p>3 A. 2011.</p> <p>4 Q. I think you've said this before,</p> <p>5 how long was the Madison Memory Study?</p> <p>6 MS. METZINGER: Objection.</p> <p>7 Form.</p> <p>8 MR. WONE: Sorry. I'll rephrase</p> <p>9 that.</p> <p>10 BY MR. WONE:</p> <p>11 Q. What was the study period in the</p> <p>12 Madison Memory Study?</p> <p>13 A. The entire study took 90 days.</p> <p>14 MS. METZINGER: Mr. Wone, we've</p> <p>15 been going for about another hour and a</p> <p>16 half. I just wanted to get a sense of</p> <p>17 when you think you might want to take</p> <p>18 the next break.</p> <p>19 MR. WONE: I've got a handful of</p> <p>20 questions more, and then I think we can</p> <p>21 break for lunch.</p> <p>22 MS. METZINGER: Okay.</p> <p>23 MR. WONE: Is that okay?</p> <p>24 MS. METZINGER: That's fine with</p> <p>25 me.</p>	<p style="text-align: right;">147</p> <p>1 form.</p> <p>2 THE WITNESS: I'm sorry. Can</p> <p>3 you rephrase that question, please,</p> <p>4 Mr. Wone?</p> <p>5 BY MR. WONE:</p> <p>6 Q. Sure.</p> <p>7 What is the year depicted in the</p> <p>8 first sentence or the first paragraph of</p> <p>9 Exhibit MK6?</p> <p>10 A. What is the year depicted?</p> <p>11 Q. Yes. Yes.</p> <p>12 A. 2010.</p> <p>13 Q. So if the study was still being</p> <p>14 conducted in 2010, is it possible for an</p> <p>15 investigator to analyze preliminary data without</p> <p>16 breaking the blinding?</p> <p>17 MS. METZINGER: Objection to</p> <p>18 form.</p> <p>19 THE WITNESS: The blinding has</p> <p>20 to be broken, but there are ways to do</p> <p>21 it that secures the blindness of the</p> <p>22 study, and we did that in the green tea</p> <p>23 trial. What you do is you have a</p> <p>24 statistician who's not intimately</p> <p>25 involved with the study do the analysis</p>
<p style="text-align: right;">146</p> <p>1 Dr. Kurzer, does that work for</p> <p>2 you?</p> <p>3 THE WITNESS: Absolutely.</p> <p>4 MS. METZINGER: Thank you.</p> <p>5 BY MR. WONE:</p> <p>6 Q. Okay. I've introduced and</p> <p>7 marked Exhibit MK6.</p> <p>8 (Marked Exhibit MK6.)</p> <p>9 BY MR. WONE:</p> <p>10 Q. Do you see that, Dr. Kurzer?</p> <p>11 A. Yes, I do.</p> <p>12 Q. Does this document, MK6, relate</p> <p>13 to the Madison Memory Study?</p> <p>14 A. Yes, it does.</p> <p>15 Q. Does Exhibit MK6 mention an</p> <p>16 interim analysis?</p> <p>17 MS. METZINGER: Objection to</p> <p>18 form.</p> <p>19 THE WITNESS: It talks about</p> <p>20 preliminary data.</p> <p>21 BY MR. WONE:</p> <p>22 Q. And what -- what is the year</p> <p>23 depicted on the document in Exhibit MK6 in the</p> <p>24 first paragraph?</p> <p>25 MS. METZINGER: Objection to</p>	<p style="text-align: right;">148</p> <p>1 so that the investi- -- the real</p> <p>2 purpose of blinding isn't so much to</p> <p>3 blind the investigators of -- of</p> <p>4 preliminary results, it's to blind</p> <p>5 investigators to which person is on</p> <p>6 which treatment. That's what you don't</p> <p>7 want the investigators or the people to</p> <p>8 know. And interim unblinding can be</p> <p>9 done in a way in which the</p> <p>10 investigators are kept blinded to who</p> <p>11 is taking what.</p> <p>12 I'll tell with you the green tea</p> <p>13 study, when we did that, it was</p> <p>14 enormously frustrating for me because I</p> <p>15 desperately wanted to know, you know.</p> <p>16 But nobody could know until the end of</p> <p>17 the study. We -- the participants</p> <p>18 wanted to know. They were emailing us</p> <p>19 and saying "I think I'm on this because</p> <p>20 I'm having these effects." We could --</p> <p>21 we had no idea. Until the very end of</p> <p>22 the study we had no idea. In fact, we</p> <p>23 didn't unblind the study until, you</p> <p>24 know, after -- you know, after we had</p> <p>25 the results in terms of us knowing</p>

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1 which person was on which treatment.

2 That's the real purpose of
3 blinding, and it's very -- it's
4 entirely possible to maintain that even
5 with an interim analysis.

6 BY MR. WONE:

7 **Q. And do you know whether those**
8 **safeguards to prevent that were done in the**
9 **Madison Memory Study?**

10 A. I don't know. I assume that
11 they were because they say that it was a blinded
12 study. So my assumption when reading it is that
13 they did it properly and did not unblind it to
14 them -- to the -- to the people who were working
15 with the participants, interpreting the data, et
16 cetera.

17 **Q. But you haven't reviewed any**
18 **documents to inform you as to how the blinding was**
19 **broken for the preliminary --**

20 A. No.

21 **Q. -- analysis?**

22 A. I do not -- right, I have not
23 seen any documents --

24 MS. METZINGER: Objection to
25 form.

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1 THE WITNESS: -- related to
2 that.

3 BY MR. WONE:

4 **Q. Does the document in Exhibit MK6**
5 **mention the AD8 0-1 subgroup?**

6 A. They do not mention the -- the
7 AD8 subgroup. They do say in the second paragraph
8 that Prevagen is a new tool for staying
9 cognitively fit, which to me means that the people
10 in the study started out cognitively fit. I think
11 that's the main point.

12 In this kind of a press release,
13 it would be way more detail than people would be
14 interested in to hear something about AD8 0-2.
15 They'd have to then explain what that means.
16 That's -- that's something that is more
17 appropriate for a much more detailed scientific
18 report. For this kind of thing, you would not
19 expect to see that.

20 **Q. Do you know whether the data**
21 **that's reported in Exhibit MK6 was from a specific**
22 **subgroup?**

23 MS. METZINGER: Objection to
24 form.

25 THE WITNESS: I do not know for

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1 sure. But as I said a few minutes ago,
2 because they talk about staying
3 cognitively fit, my interpretation of
4 this is that the people in this study
5 started out cognitively fit.

6 BY MR. WONE:

7 **Q. So the data that's depicted**
8 **could be from the 0-2 group, right?**

9 A. Yes.

10 **Q. It could be also from the 0-1**
11 **group --**

12 A. Yes.

13 **Q. -- right?**

14 **And it also could be some**
15 **other -- some other group, correct?**

16 A. Correct. And this is -- this
17 is -- this is not a scientific report, so I would
18 not expect the level of -- of rigor that you might
19 expect in a scientific paper. I just -- you just
20 wouldn't.

21 **Q. And if the procedures that you**
22 **discussed earlier to maintain blinding during a**
23 **preliminary analysis were not -- were not**
24 **followed, would that affect how you would**
25 **interpret the results?**

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1 MS. METZINGER: Objection to
2 form.

3 THE WITNESS: Can you rephrase
4 that question, please, for me?

5 BY MR. WONE:

6 **Q. Sure.**

7 **Earlier you discussed procedures**
8 **that -- that an investigator could use to maintain**
9 **blinding during a preliminary or interim analysis,**
10 **right?**

11 A. Yes.

12 **Q. And so if those procedures were**
13 **not followed, would it affect how you interpret**
14 **the result?**

15 MS. METZINGER: Objection to
16 form.

17 THE WITNESS: You know, it would
18 depend. You -- I -- it might or it
19 might not. There are levels of rigor
20 that vary across studies. And I think
21 that applying this very, very high
22 level of rigor that I would say applies
23 to a drug trial or an NIH-funded study
24 is just not appropriate for this kind
25 of dietary supplement that the -- I --

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1 my understanding is that the FTC
2 guidance allows for much more
3 flexibility in interpretation of
4 research used to substantiate claims.

5 And so, you know, I would be
6 much more concerned about some of the
7 things that you're talking about and
8 some of the things that you've asked me
9 about if this was a drug trial and
10 with -- with very serious implications,
11 very serious cost if -- if there are
12 errors, very serious health -- adverse
13 health events if there are errors, et
14 cetera.

15 But for something that's safe
16 and is a nutritional supplement meant
17 to supplement the body's intake of
18 food, I just wouldn't be nearly as
19 concerned with some of the kinds of
20 things that you're asking me about
21 as -- as -- as you might be -- as I
22 would be if it were a drug trial.

23 I know that's not exactly a
24 direct answer to your question, but,
25 you know, I just wanted to say that

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1 can't blind soy protein. There isn't
2 something else that you can give that
3 is not identified -- not -- that cannot
4 be distinguished. Soy protein has a
5 flavor. People who are take --
6 drinking a soy protein drink, no. And
7 so in my soy protein studies, we --
8 we've used casing milk protein as the
9 control. And neither we nor the
10 participants were blinded. They knew.
11 We didn't tell them, but they knew
12 because they could taste the
13 difference. So they knew if they were
14 consuming the soy. And that was really
15 the only way to do the study. There
16 isn't -- when you're doing a study with
17 foods, there isn't a way to blind the
18 participants and -- or the -- or the
19 researchers. And yet, I think it's
20 still a very rigorous -- it was still a
21 very -- those are still rigorous
22 studies published in very, very good
23 scientific journals having gone through
24 extensive peer review.
25

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1 because you're asking me about
2 interpreting and would I be worried
3 about this.

4 And, you know, if -- if -- if
5 they had unblinded themselves in this
6 study, that might be a little bit of a
7 concern, but it can still be a very,
8 very well-done study. In fact, I think
9 that requiring blinding is a very
10 extreme requirement that, in many
11 cases, is not necessary in -- in -- on
12 a level of scientific rigor and
13 accuracy that blinding -- the study
14 would -- the results would still be
15 accurate if the study were blinded.

16 BY MR. WONE:

17 **Q. Would you describe the RCTs that**
18 **you've conducted in your career as being**
19 **methodologically rigorous?**

20 MS. METZINGER: Objection to
21 form.

22 THE WITNESS: I think that they
23 have, but they have not all been
24 blinded. So, for example, the soy
25 protein studies that I've done, you

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1 BY MR. WONE:

2 **Q. And those studies that didn't**
3 **have blinding, the lack of blinding was part of**
4 **their design. That was how they were designed,**
5 **correct?**

6 A. Yes. We knew in the beginning
7 that they wouldn't -- that it wouldn't be blinded.

8 **Q. And the RCTs you worked on**
9 **involved health claims for nutritional**
10 **supplements, correct?**

11 MS. METZINGER: Objection to
12 form.

13 THE WITNESS: The RCTs that I've
14 worked on and the clinical trials that
15 I've worked in -- on that weren't --
16 that weren't necessarily blinded have
17 involved the effect of dietary
18 constituents which could be considered
19 supplements, but soy protein isn't
20 exactly a supplement, but it's a --
21 it's a food constituent on various
22 health endpoints.

23 BY MR. WONE:

24 **Q. You've also worked on RCTs that**
25 **were blinded and did involve a dietary supplement?**

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1 A. Yes, particularly the green tea
2 study that I was talking about. In that case, we
3 gave pills, and the pills for the placebo and the
4 treatment group were identical, and they were
5 blinded and we were blinded.

6 **Q. And would you agree that**
7 **blinding -- double-blinding is something that's**
8 **possible with a dietary supplement like Prevagen?**

9 MS. METZINGER: Objection --

10 THE WITNESS: Yes --

11 MS. METZINGER: -- to form.

12 THE WITNESS: -- it is.

13 BY MR. WONE:

14 **Q. I'm sorry. I didn't hear your**
15 **answer, Doctor.**

16 A. Yes.

17 MR. WONE: Okay. I think we can
18 go off the record.

19 THE VIDEOGRAPHER: We are going
20 off the record at 12:15 P.M.

21 (Off the record from 12:15 until
22 1:01.)

23 THE VIDEOGRAPHER: We are going
24 back on the record at 1:01 P.M.
25

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1 BY MR. WONE:

2 **Q. Good afternoon, Dr. Kurzer.**

3 A. Good afternoon, Mr. Wone.

4 **Q. I'd like to go back to some**
5 **things that we talked about earlier this morning.**

6 A. Sure.

7 **Q. If you could go back to your**
8 **report, what's been marked as Exhibit MK1 --**

9 A. Yes.

10 **Q. -- paragraph 33, please.**

11 A. Yes. I have it here.

12 **Q. Do you see in the second line**
13 **where you discussed the initial publication that**
14 **it was discovered that transformation and data set**
15 **errors had been made in the data analysis?**

16 A. Yes, I see that.

17 **Q. I was wondering what -- what do**
18 **you mean by "transformation"?**

19 A. I don't know what the exact
20 problem was. This is a very long time ago and
21 I -- I don't recall getting into the details about
22 it. There -- the way that the data were analyzed
23 I guess involved some kind of transformation, and
24 I'm not sure what the transformation was. And
25 that was caught later on. So I really can't

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1 answer that. I'm sorry.

2 **Q. Do you have any recollection as**
3 **to what the data set errors were?**

4 A. No, I don't. I don't remember.

5 I think I -- I think we talked about it. I may
6 have talked about it at the time, but I just don't
7 remember right now.

8 **Q. Did you review any documents**
9 **that would have told you what those transformation**
10 **or data set errors were?**

11 A. No, I did not.

12 **Q. Earlier this morning, it's my**
13 **understanding, you testified that it's your belief**
14 **that Prevagen is intended for healthy older**
15 **adults; is that right?**

16 A. Yes, it is.

17 **Q. And so if Prevagen is intended**
18 **for healthy older adults, when you were conducting**
19 **your literature search, why did you use the term**
20 **"Alzheimer's"?**

21 A. Why did I use the term
22 "Alzheimer's." Because sometimes cognitive
23 decline and cognitive function is evaluated in a
24 larger setting in which Alzheimer's is also
25 evaluated. So I wanted to pick up the broadest

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1 number of papers that I could. I wasn't
2 interested in Alzheimer's as an endpoint, per se.
3 But the purpose of a literature review is to pull
4 in as many papers as you can and then select from
5 them the ones that you think are the most
6 appropriate.

7 **Q. And would that also be the**
8 **reason why you included dementia in your**
9 **literature search?**

10 A. Exactly. I wasn't sure how much
11 I would get from just looking at cognitive
12 function or cognitive decline because what you get
13 from a literature review is dependent upon the
14 keywords that the authors of the papers put in,
15 and so sometimes you miss things because the key
16 word isn't exactly right. So that is the reason.

17 **Q. And if Prevagen is intended for**
18 **healthy older adults, why did you discuss**
19 **Alzheimer's disease in paragraph 25 of your**
20 **report?**

21 A. The reason I discussed it is
22 because Alzheimer's disease is the -- the end of
23 the spectrum of cognitive decline. And when
24 people who experience the mild cognitive decline
25 and early signs, it often progresses to full-on

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1 Alzheimer's disease. And so because Alzheimer's
2 disease is such an incredible concern in the
3 United States in terms of cost socially and
4 financially, anything that can slow the decline of
5 cognitive function might wind up reducing this
6 very devastating end result or slowing its
7 progression. So I thought it was interesting to
8 put in something about Alzheimer's disease to give
9 the context in which this particular problem of
10 mild cognitive decline is -- is important. It's
11 just to fill out the context.

12 **Q. And would that be the same**
13 **reason why you included paragraph 24 on dementia?**

14 A. Yes.

15 **Q. And are you offering any**
16 **opinions related to the efficacy of Prevagen and**
17 **dementia?**

18 A. No.

19 **Q. How about are you referring any**
20 **opinions related to the efficacy of Prevagen and**
21 **Alzheimer's disease?**

22 A. No, I'm not. I -- I'm offering
23 opinions on the efficacy of Prevagen for mild
24 cognitive dysfunction and the -- you know, a
25 mild -- the milder level of decline. Dementia --

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1 **Q. When you say --**

2 A. Dementia is a further
3 deterioration, and then Alzheimer's disease is one
4 cause of dementia, but then there are other causes
5 as well.

6 **Q. When you say "mild cognitive**
7 **dysfunction," is that the same thing as mild**
8 **cognitive impairment --**

9 A. Yes.

10 **Q. -- that you discuss in**
11 **paragraph 23?**

12 A. Yes.

13 **Q. So you are offering opinions in**
14 **your report related to Prevagen and mild cognitive**
15 **impairment?**

16 A. Yes. I think that -- you know,
17 it may -- it may be difficult to -- to form a red
18 line between the normal cognitive decline of aging
19 and mild cognitive impairment. The point is
20 that -- that the question is will Prevagen help
21 slow or reduce this trajectory.

22 **Q. So are you offering opinions**
23 **that Prevagen slows the progression of mild**
24 **cognitive impairment?**

25 MS. METZINGER: Objection to

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1 form.

2 THE WITNESS: I think that I
3 wouldn't make the claim. I wouldn't
4 necessarily support a claim related to
5 mild cognitive impairment because that
6 would be a disease claim. So I used
7 evidence on mild cognitive impairment
8 to support the idea that Prevagen has a
9 beneficial effect on cognitive decline.
10 But I wouldn't support a claim for
11 preventing mild cognitive impairment or
12 Alzheimer's disease or dementia because
13 those are disease claims not permitted
14 under the guidance.

15 BY MR. WONE:

16 **Q. Which guidance are you referring**
17 **to?**

18 A. FTC guidance, FDA guidance
19 related to claims that are permitted. This is a
20 structure function claim, not a disease claim.

21 **Q. Earlier when we were talking**
22 **about the Madison Memory Study, I believe you**
23 **mentioned that there would be legitimate reasons**
24 **to include people who scored a 3 or above on the**
25 **AD8. Do you remember that?**

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1 MS. METZINGER: Objection to
2 form.

3 THE WITNESS: I believe that I
4 said there that investigators might
5 have a reason to recruit those folks
6 into the study.

7 BY MR. WONE:

8 **Q. And what would be some of those**
9 **reasons?**

10 A. Well, one reason for
11 over-recruitment is to -- to account for dropouts.
12 That could be 20 or 25 percent extra that you
13 recruit because you want to have a final number of
14 a hundred, so you might have to recruit 25 percent
15 extra.

16 It's possible, and I don't know
17 this because I haven't spoken with the
18 researchers, so I don't know, but I could imagine
19 that are situations where, when a clinical trial
20 is being done, it's very expensive and very -- as
21 I said, very time consuming, that with thinking
22 towards the future, that an investigator might
23 say, "Well, let's just kind of do the study on --
24 on everybody because maybe in the future, if it
25 turns out we have people who have more serious

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1 cognitive decline, we'll want to look at those
2 results." But for now, those -- that -- that --
3 those data are just going to be sitting because
4 it's not our primary concern.

5 So I could imagine doing that as
6 a scientist, trying to make the most of the
7 resources that I have. I could imagine doing
8 that.

9 **Q. And in connection the Madison**
10 **Memory Study, did you ever look at any data for**
11 **participants who scored 3 and above on the AD8?**

12 A. I -- I believe that might have
13 been in one of the papers. I -- I guess I'm not
14 sure -- I'm not sure right now if I did. I guess
15 in the Advances paper they have data on AD8 2-5.
16 So they do those show those data in that paper.

17 **Q. Is it your understanding that**
18 **the Advances paper was written before the data set**
19 **was -- before the errors in the data set were**
20 **identified?**

21 A. Yes.

22 **Q. And so you don't know whether**
23 **the data that's presented in the Exhibit MK4 is**
24 **accurate or not?**

25 MS. METZINGER: Objection to

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1 Whether the results differ, I don't
2 know.

3 BY MR. WONE:

4 **Q. Okay. If a study had been**
5 **unblinded through an interim analysis and the**
6 **principal investigator had access to the**
7 **information as to -- the data including what**
8 **groups people were assigned to, would you agree**
9 **that the study would no longer be considered**
10 **double-blinded?**

11 MS. METZINGER: Objection. Are
12 you talking about any study or the
13 Madison Memory Study?

14 MR. WONE: Hypothetically.

15 MS. METZINGER: Objection to
16 form.

17 THE WITNESS: Hypothetically if
18 a study were unblinded and the
19 researchers knew who was taking which
20 and/or the participants knew who were
21 taking -- who was taking what, it would
22 no longer be a blinded study.

23 BY MR. WONE:

24 **Q. I believe you testified**
25 **earlier --**

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1 form.

2 MR. WONE: I'll rephrase.

3 BY MR. WONE:

4 **Q. Do you know whether the data**
5 **depicted in Exhibit MK4 was accurate?**

6 MS. METZINGER: Objection to
7 form.

8 THE WITNESS: I don't know. You
9 know, once I found out that there were
10 errors, then I focused my attention on
11 the corrected data and the results that
12 were -- that were generated by the
13 corrected data. So I don't know if
14 that first paper is correct or not.
15 I -- I didn't focus most of my
16 attention on that.

17 BY MR. WONE:

18 **Q. So you don't know whether**
19 **Exhibit MK4 has corrected data?**

20 MS. METZINGER: Objection to
21 form.

22 THE WITNESS: I've been told
23 that the data was corrected after this
24 paper was published, so my assumption
25 is that this is the precorrected data.

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1 A. Mr. Wone -- Mr. Wone --

2 **Q. Yes?**

3 A. -- if I could add something to
4 that?

5 **Q. Sure.**

6 A. Just to sort of repeat something
7 that I said before, the fact that it is not a
8 blinded study does not mean that the results are
9 useless. The results may still be accurate even
10 if it is not a double-blind study.

11 **Q. Are you distinguishing between a**
12 **study that was -- that's not blinded from the**
13 **outset versus a study that was double-blinded but**
14 **in which -- for which the blinding was broken?**

15 A. I'm not distinguishing, no, no.
16 I'm -- I'm saying that a blinding of the study is
17 a very, very high threshold that's set for drugs
18 and is important to stick to for studies like drug
19 trials. But in my experience and in my opinion, I
20 don't think that the results of an unblinded study
21 or a not blinded study are false results. I've --
22 as I said before, I've published numerous papers
23 from studies I've done that were not blinded, and
24 I stand behind those results fully.

25 **Q. If a study was unblinded and the**

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1 **investigators knew which participants who were**
 2 **assigned to each of the groups, could the data --**
 3 **could the data from that study be biased?**

4 MS. METZINGER: Objection to
 5 form.

6 THE WITNESS: That really
 7 depends on who is made aware of the
 8 data. If it's the principal
 9 investigators who are not interacting
 10 with the participants, that may not
 11 have any effect at all. I would be
 12 more concerned if it was the study
 13 coordinator, the person who is, for
 14 example, giving the tests directly to
 15 the participants. If they -- if that
 16 person, that staff member knew who was
 17 in which group, I might be concerned
 18 about that.

19 But I wouldn't -- if -- if it's
 20 a principal investigator who, like me,
 21 is a number of levels away from the
 22 participants, my knowledge isn't going
 23 to have any effect on the results.

24 BY MR. WONE:

25 **Q. Could it have an effect on how**

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1 **the investigators were doing the analysis**
 2 **themselves?**

3 MS. METZINGER: Objection to
 4 form.

5 THE WITNESS: No, my opinion
 6 would not change.

7 BY MR. WONE:

8 **Q. I think we also mentioned that**
 9 **it was your understanding that the Madison Memory**
 10 **Study was 90 days?**

11 A. Yes.

12 **Q. And what was the basis for your**
 13 **belief?**

14 A. I think it's stated in the
 15 protocol that it's a 90-day study. And in the
 16 publication, it's -- the study is described as a
 17 90-day study, so I think it's very clear. I'm
 18 looking at the protocol now, and study duration,
 19 90 days. And it says the same thing in the
 20 manuscripts.

21 **Q. Okay. In your expert report,**
 22 **Exhibit MK1, you discussed corrections, correct?**

23 A. Can you --

24 MS. METZINGER: Objection to
 25 form.

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1 **you interpret the data?**

2 MS. METZINGER: Objection to
 3 form.

4 THE WITNESS: The concern I
 5 would have would not be with the
 6 interpretation of data because when --
 7 when I have a data set as a principal
 8 investigator, when I'm working on a
 9 data set with a statistician, I -- it's
 10 all numbers. The data is de-identified
 11 in the data analysis. So I have no
 12 idea who any individual person is.

13 The concern I would have here is
 14 in the administration of the cognitive
 15 tests if the person who is
 16 administering the test knows which
 17 group that participant is in, their
 18 interpretation of the results might be
 19 affected by that. Theoretically, it
 20 could be. But I would not at all be
 21 concerned at the level of data analysis
 22 working with a data set.

23 BY MR. WONE:

24 **Q. Would your opinion change if**
 25 **there wasn't a statistician analyzing the data and**

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1 THE WITNESS: Can you tell me
 2 which paragraph that is, please?

3 BY MR. WONE:

4 **Q. I'm looking at paragraph --**
 5 **sorry. Looking at Section 8.**

6 A. Is there a -- okay. Section 8,
 7 issues related to the use of Bonferroni. Yes.

8 **Q. What is the correction in this**
 9 **context?**

10 A. The correction in this context
 11 is a correction for multiple comparisons, the idea
 12 being that when you do many, many, many
 13 comparisons, that some of those will show a
 14 significant effect by chance because you're doing
 15 so many.

16 And so in some situations,
 17 statisticians view -- feel that it's important to
 18 basically reduce your p-value so that you make it
 19 more difficult to find a significant effect in
 20 order to correct for the fact that there might be
 21 some random effects that you see because of the
 22 number of tests that you've done. That's my
 23 understanding.

24 **Q. And what are some situations**
 25 **where you feel a correction would be appropriate?**

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1 A. I think that Bonferroni -- I
2 would be -- I'm very, very reluctant to take a
3 general stand on Bonferroni. I think that it
4 really needs to be decided on individual cases.
5 It's a very, very strict requirement and it's
6 fairly controversial.

7 And in the same sense that a
8 p-value is an arbitrary number, an arbitrary
9 cutoff, Bonferroni decreases the false positives,
10 but it can have a big increase in false negatives.
11 So it can reduce your ability enormously to see
12 a -- to see an effect.

13 So I'm sure that there are
14 situations with clinical drug trials where there's
15 the impact of a mistake on -- in the data analysis
16 is so critically important that you want to avoid
17 false positives at any -- you know, you want to
18 avoid at all cost false positives.

19 So, for example, you know, if
20 you have a drug that's going to cure cancer, you
21 know, you don't want false positives because you
22 don't want to approve this drug and you -- you
23 want to make it hard to see an effect for yourself
24 because you don't want it to be approved unless
25 you are a thousand percent sure that it's going to

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1 work. In that situation, I can see that a
2 correction would be appropriate to do.

3 The problem with Bonferroni, as
4 I say in my report, and I think it's a significant
5 problem, is that if you really believe in
6 Bonferroni and you feel that it should be used in
7 every situation, then what will happen is in most
8 cases we will never, ever be able to find a
9 significant result for anything because even with
10 some of the most widely respected and publicized
11 and published clinical studies or epidemiological
12 studies, there may be many, many, many papers
13 published.

14 So, for example, the AREDS
15 trial, which is an eye health -- eye supplement
16 trial, there are at least 30 or 40 or 50 papers
17 that have been published. And when people report
18 data in the beginning, they don't account for
19 future papers. They don't account -- you know, if
20 we were to go back, okay, and say now that the 50
21 papers have been published, let's redo the
22 statistics knowing how many different -- different
23 analyses we did, nothing would be significant.
24 We'd find zero significance.

25 And so people -- people tend

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1 to -- researchers tend to break their studies down
2 into pieces in part because it's digestible for
3 the reader. You just don't want to publish papers
4 where you have so much in there that it's
5 overwhelming.

6 You need to have theme to your
7 paper. So you might publish your lipid results in
8 one paper and your hormone results in another
9 paper, and then you might publish some other --
10 you don't account for all of the comparisons in
11 every paper. You can't do it because you
12 aren't -- you know, you don't know in advance.

13 And so really if you take
14 this -- if you take the Bonferroni -- if you
15 believe that it should be used in every situation,
16 then I think you have a real problem with finding
17 any significant results at all.

18 But as I said, in the case of a
19 situation like a drug that is critically important
20 for peoples lives, you want to make sure that you
21 reduce the pos- -- false positive as much as
22 possible and you don't care so much about the
23 false negatives.

24 So there's -- you know, it
25 really depends on the situation, in my opinion.

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1 And in this situation where we're talking about a
2 dietary supplement, which has very little -- which
3 has no adverse effects, which is something which
4 may confer some benefit to some people, I'm not
5 worried about the false positive rate. I just
6 wouldn't be worried about it in this situation.
7 And the FTC guidance on regulating -- you know, on
8 advertising for dietary supplements specifically
9 gives a lot of flexibility and suggests to me --
10 my interpretation of the guidance is that the kind
11 of rigor that's applied to clinical trials is
12 to -- to drugs is not necessary for dietary
13 supplements.

14 And so while in a clinical trial
15 of a -- of a drug that is potentially going to
16 lengthen or save someone's life who has cancer, I
17 might in that case say, no, I agree that
18 Bonferroni should be used. But in this case, I
19 think it's really overkill. It's -- it's way,
20 way, way more than necessary.

21 **Q. You mentioned one particular**
22 **type of correction, Bonferroni correction.**

23 A. Mm-hmm.

24 **Q. Are there other types of**
25 **corrections?**

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1 A. There -- I believe that there
2 are many types of corrections. And the one that
3 I've used when I have used a correction has been
4 Bonferroni, so that's the one that I'm the most
5 familiar with, but they're all variations on the
6 same theme. They're all versions of the same type
7 of correction, which is basically reducing your
8 p-value threshold to account for the number of
9 comparisons that you're making.

10 **Q. And in the example you just gave**
11 **in your prior answer, you mentioned researchers**
12 **will have different papers, for example, a lipid**
13 **paper. And so in that lipid paper, would you use**
14 **a correction to account for multiple comparisons?**

15 MS. METZINGER: Objection to
16 form.

17 THE WITNESS: It depends on the
18 number of comparisons that I've done,
19 and it depends on the statistician who
20 I'm working with and what their view is
21 because very well-respected,
22 well-trained professional statisticians
23 differ on this point. And so I take
24 the advice often from the statistician
25 with whom I'm working, and so it really

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1 would depend on the individual case.

2 There are many statisticians,
3 and I have worked with a number of
4 statisticians, and I find that the
5 statisticians who have the most
6 experience with biological data, with
7 human data, are much more flexible in
8 interpreting statistical results
9 because of the things that we talked
10 about before.

11 BY MR. WONE:

12 **Q. And you've mentioned you --**
13 **you've used Bonferroni in your own research,**
14 **correct?**

15 A. I believe that I have. I'd have
16 to look at my papers to see where I might have
17 used it, but I -- I probably have used some kind
18 of multiple -- multiple comparison testing,
19 multiple comparison correction. But not very
20 often for the reasons that I said because it
21 really reduces your ability to see a true effect.

22 **Q. So I'm introducing what's been**
23 **marked as Exhibit MK7.**

24 A. Yep.

25 **Q. Do you see that, Doctor?**

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1 A. I do.

2 (Marked Exhibit MK7.)

3 BY MR. WONE:

4 **Q. And it this one of your research**
5 **papers, Doctor?**

6 A. It is. It's a paper from
7 20 years ago, I see. And my students are on it
8 who I'm very proud of. Alison is a full professor
9 now, so, yes.

10 **Q. If you could turn to page 227 of**
11 **that, of Exhibit MK7. I'm referring to the page**
12 **numbers that are depicted in the top right corner.**

13 A. 227, yes. Yes.

14 **Q. Do you see the data analysis**
15 **section?**

16 A. Yes.

17 **Q. And the second paragraph of that**
18 **section, do you see a mention of the Bonferroni**
19 **correction?**

20 A. Yes.

21 **Q. And do you see that the**
22 **Bonferroni correction was applied to p-values to**
23 **adjust for multiple comparisons?**

24 A. Yes.

25 **Q. And what were the comparisons**

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1 **being made in this study in Exhibit MK7?**

2 A. So we were looking at three
3 different diets, and we were looking at LDL peak
4 particle diameter, LDL -- and concentrations of
5 triacylglycerol apo A-1, apo B, lipoprotein(a),
6 total ADL and HDL cholesterol. So there were
7 eight different endpoints and three different
8 diets so that each of the diets was compared with
9 each of the other diets.

10 **Q. And why did you use the**
11 **Bonferroni construction in this study?**

12 A. I use the Bonferroni correction
13 in this study because the statistician I was
14 working with probably insisted that I use it
15 because that was his belief, and so I agreed that
16 we would use it. But if I had been working --
17 frankly, if I had been working with a different
18 statistician, they might have said we don't need
19 to.

20 But this is probably more
21 comparisons than I often do in my studies, and so
22 it was -- I accept this recommendation.

23 **Q. And do you know whether the**
24 **comparisons in this study were correlated?**

25 A. Yeah, I think that some of them

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1 are. Yes, some of them are correlated. Not all
2 of them.

3 **Q. And did this study involve a**
4 **dietary ingredient?**

5 A. Yes. It involved soy -- soy
6 protein intervention.

7 **Q. And what were you studying in**
8 **this article in relation to soy?**

9 MS. METZINGER: Objection to
10 form.

11 THE WITNESS: What's that?

12 Excuse me? Can you ask --

13 BY MR. WONE:

14 **Q. What were you studying in**
15 **Exhibit MK7 in connection to soy?**

16 A. Oh, we were looking at the
17 effect of soy protein consumption on plasma
18 lipids.

19 **Q. Did the study involve any**
20 **investigation of a disease?**

21 A. No. No, it didn't. It -- we
22 looked at lipid levels in the blood which relate
23 to disease but are not a disease endpoint
24 themselves.

25 **Q. And did the study depicted in**

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1 **MK7 involve a drug?**

2 A. No, it didn't. It involved a
3 food or, you know, dietary substance.

4 **Q. So I'd like to introduce what**
5 **has been marked as Exhibit MK8.**

6 **(Marked Exhibit MK8.)**

7 THE WITNESS: Okay.

8 BY MR. WONE:

9 **Q. Do you see that, Doctor?**

10 A. I do.

11 **Q. And were you an author on this**
12 **study in Exhibit MK8?**

13 A. Yes.

14 **Q. And what did this study in**
15 **Exhibit MK8 involve?**

16 A. This involved the evaluation of
17 consumption of green tea, green tea extract with
18 the bioactives in green tea, the effect on serum
19 lipids in postmenopausal women.

20 **Q. And green tea extract is a**
21 **dietary ingredient?**

22 A. Yes, it is.

23 **Q. And the study depicted in**
24 **Exhibit MK8 did not involve a disease, correct?**

25 A. That's correct.

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1 **Q. If you could turn to page 1673**
2 **in Exhibit MK8. And I'm referring to the page**
3 **numbers on the top corners of the page.**

4 A. Yes.

5 **Q. In the right hand column, the**
6 **last paragraph before the result section, do you**
7 **see that, Doctor?**

8 A. Yes.

9 **Q. And do you see in the last**
10 **sentence that the Bonferroni correction was used**
11 **to adjust for multiple comparisons?**

12 A. Yes.

13 **Q. Why did you apply the Bonferroni**
14 **correction in the study depicted in Exhibit MK8?**

15 A. Again, I was working with a
16 statistician whose name is Renwei Wang, and
17 Jiamin Yuan, who are -- their experience is with
18 enormous data sets. They're epidemiologists, and
19 their experience is with huge data sets in which
20 they look at every dietary substance that the
21 person consumes in relation to cancer risk. They
22 may do hundreds and hundreds and hundreds of
23 comparisons in their papers.

24 So my opinion is that this is a
25 standard practice for them, and they have -- I

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1 don't believe they had ever done a clinical trial
2 before this. They were using statistical methods
3 that were -- that are probably more conservative
4 than necessary, but I accepted it because I -- you
5 know, I -- I relied on them and I didn't argue
6 with them. They also were difficult to argue with
7 as far as people. And so I accepted that
8 correction. I'm not sure that it was necessary
9 for this particular paper.

10 In addition, this was one of
11 those studies that was not in the original
12 protocol. So the original protocol did not have
13 lipids in it. There wasn't part -- we added it on
14 because during the study, we realized that there
15 is some evidence that green tea may be associated
16 with beneficial effect on blood lipids, and so we
17 decided to add this on. It didn't change our
18 statistics. We did comment that it was an
19 ancillary study so that this was -- and we did a
20 subgroup analysis as well, I recall. We looked at
21 hypercholesterolemic women as well as normal
22 cholesterolemic women. I believe we separated
23 them out. Hang on one second.

24 Well, we looked at the -- in
25 table 5 on page 1679, you can see that we looked

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1 at blood lipids stratified by baseline BMI because
2 we thought that could be a factor that is
3 important to take into effect.

4 On the next table, 6, we
5 actually also separated out those who used statin
6 from those who didn't because we thought that is
7 probably an important factor. It wasn't something
8 we thought about in the beginning of the study
9 because we weren't planning on looking at lipids,
10 so statins weren't something that we were thinking
11 about.

12 So this is something that we
13 added on and that we did do subgroup analysis
14 because ultimately -- my philosophy is -- and a
15 very, very strict statistician might disagree with
16 me, but I'm more concerned with getting the truth
17 and getting the result that's real and important
18 that I am about whether or not a particular test
19 which may or may not be appropriate for this data
20 set is used.

21 So, for example, looking at
22 people who are taking statins versus people who
23 aren't seemed like a really important way to look
24 at the data.

25 **Q. And you noted in the study**

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1 **report in Exhibit MK8 that this was an ancillary**
2 **study?**

3 A. Yes. But it didn't affect how
4 we did the statistics, but we did note that so
5 that the reader could see.

6 **Q. And when you applied the**
7 **Bonferroni correction to the comparisons, do you**
8 **know whether the comparisons in the study in**
9 **Exhibit MK8 were correlated?**

10 MS. METZINGER: Objection to
11 form.

12 THE WITNESS: I don't -- I don't
13 remember. I'm -- I'm sorry, I don't
14 remember that. I'd have to --

15 BY MR. WONE:

16 **Q. What were the --**

17 A. -- study the paper a little
18 more.

19 **Q. What were the comparisons that**
20 **were being made in -- in Exhibit MK8?**

21 A. Okay. So we were looking at the
22 effect of green tea extract on total cholesterol,
23 HDL cholesterol, and triglycerides. And we had
24 the placebo group and we had the treatment group,
25 and we also stratified by a genotype, a genetic

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1 polymorphism in the COMT gene which we thought
2 might affect metabolism of catechins and,
3 therefore, the biological effect of catechins.

4 **Q. And do you know whether**
5 **triglycerides and HDL are correlated?**

6 A. You know, right off the bat --
7 the bat, I -- I don't recall. I think we probably
8 looked for that in here. We probably did some
9 tests to determine whether or not they're
10 correlated because that would influence the
11 statistical -- the type of statistical test that's
12 used. And I don't recall. I'd have to study this
13 a little bit.

14 **Q. You can look through the article**
15 **if you'd like.**

16 A. Okay. Thank you.

17 I'm sorry. I don't see it. I
18 don't see that we looked for it. Unless you can
19 point me to something, I don't see that we looked
20 at correlation among those -- among those
21 endpoints.

22 **Q. Okay. When you worked --**

23 A. But I would -- I will tell you
24 that this study reflects one of the weaknesses or
25 one of the limitations of clinical trials, which

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1 is that despite the fact that we recruited a
2 thousand women and we randomized them really
3 perfectly, there was a difference in baseline
4 lipids between the two groups. It's just -- and
5 that's happened to me in other studies too. It's
6 just bad luck. And that happens. And it makes
7 your -- you know, the data analysis a little bit
8 more difficult. And it's very disappointing when
9 that happens, but that's something you find out at
10 the end of the study.

11 **Q. Okay. And when you're working**
12 **on an RCT, you rely on the statistician to decide**
13 **whether a correction is appropriate?**

14 MS. METZINGER: Objection to
15 form. Mischaracterizes the witness'
16 testimony.

17 THE WITNESS: I wouldn't say I
18 rely on a statistician. I rely on my
19 relationship with them and
20 conversations with them. So I take
21 their advice very, very seriously just
22 as when I'm a -- when I'm a
23 collaborator on a study where I'm the
24 only person who has a Ph.D. in
25 nutrition, I hope that they take my

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1 advice when I point out things. But
2 that doesn't mean they shouldn't be
3 doing the study or, you know, they --
4 they -- we don't -- we -- these days we
5 work in teams, and people have
6 different areas of expertise, so it's
7 extremely common to have -- you know,
8 to have someone -- to have a
9 statistician or a nutritionist who
10 interacts with the others and the
11 decisions are made as a group
12 collectively.

13 BY MR. WONE:

14 **Q. We can go back to your expert**
15 **report, Exhibit MK1.**

16 A. Yes.

17 **Q. And go to paragraph 47, please.**

18 A. Okay.

19 **Q. In paragraph 47, you mention the**
20 **word "correlated." Could you explain what you**
21 **meant by "correlated" in the context of**
22 **paragraph 47?**

23 A. What I meant is that they are
24 not independent of each other. They are either
25 affected by the same underlying cause or they

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1 are -- they move in parallel to each other so that
2 you would expect that an effect on one would
3 probably be similar to an effect on the other.
4 That's what I mean by "correlated."

5 **Q. Do you know whether all aspects**
6 **of cognitive function are correlated?**

7 MS. METZINGER: Objection to
8 form.

9 THE WITNESS: I don't know in
10 the statistical sense whether they're
11 correlated, but I know in the common
12 sense that they're correlated because
13 the factors, if you -- if you look into
14 detail on each of these different
15 factors and -- and I did do that for
16 this exact reason, you can see that
17 many of the same things contribute to
18 each of these endpoints. So --

19 BY MR. WONE:

20 **Q. How --**

21 A. Yeah.

22 **Q. Go on. I didn't mean to cut you**
23 **off.**

24 A. So that -- so that -- you know,
25 if attention -- as we said before, I think we

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1 talked about this before, you know, in order to
2 learn, you have to have memory. You have to have
3 a good memory to learn. You have to be able to
4 pay attention. So there's all -- there's a --
5 every -- I think that even the folks in this field
6 agree that there is overlap among these. That
7 would result in them being highly correlated.
8 They're not independent if there's overlap.

9 **Q. So you described I think what**
10 **you meant by common sense correlation, but you**
11 **distinguished it from statistical correlation.**
12 **What is the difference?**

13 A. The difference is that I haven't
14 seen the statistical data to show that these --
15 I -- I didn't pay a lot of attention when I was
16 writing this up to the statistical data showing
17 that these endpoints are statistically correlated
18 with each other because there are methods of
19 statistical analysis that can determine
20 correlation independence. And I don't recall
21 seeing those kinds of data that actually
22 statically prove the correlation. But if
23 something -- if a measurement includes pieces of
24 another measurement, it just makes sense that
25 they're correlated, they're not independent.

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1 **Q. And how do you know whether --**
2 **how do you know the level of correlation between**
3 **two things that are not independent?**

4 MS. METZINGER: Objection to
5 form.

6 THE WITNESS: That would require
7 a statistical test to be able to see
8 the level of correlation. But, you
9 know -- for example, you know, just out
10 of kind of real life, I think that I
11 can say pretty conclusively that it's
12 easier for tall people to reach my
13 upper cabinets than it is for short
14 people. I don't need to do a
15 statistical test to prove that, you
16 know. I just know that. So that's
17 where I say common sense has to come
18 into this, that if you're a
19 statistician, you're going to go, oh,
20 my, do you have enough participants and
21 have you done the right tests. There
22 are some things that are fairly
23 obvious.

24 BY MR. WONE:

25 **Q. So if I'm understanding you**

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1 **right, you believe that memory and executive**
2 **function are correlated, correct?**

3 A. Memory and executive function, I
4 would say probably. But certainly memory and
5 attention are correlated. I'm certain of that.
6 And sometimes people talk about concentration, and
7 concentration and attention seem to be very, very
8 overlapping concepts.

9 So executive function is kind of
10 unique, so I would have to think about that a
11 little bit, whether executive function would be --
12 would be related but -- to some of these others.

13 But there's a concept of working
14 memory. And they often talk about working memory
15 versus executive function. They're very, very
16 overlapping. You know, executive function is the
17 ability to manage many things in your brain at the
18 same time. And working memory is very similar.
19 It's the ability to manipulate thoughts and ideas
20 and concepts. So they're very, very similar
21 ideas.

22 **Q. And do you know the level of**
23 **correlation between memory and attention?**

24 A. I don't know the level of
25 correlation, no.

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1 **Q. Do you know the level of**
2 **correlation between working memory and executive**
3 **function?**

4 A. I do not.

5 MR. WONE: Can we go off the
6 record for a moment?

7 THE VIDEOGRAPHER: We are going
8 off the record at 1:51 P.M.

9 (Off the record from 1:51 until
10 1:52.)

11 THE VIDEOGRAPHER: We are going
12 back on the record at 1:52 P.M.

13 BY MR. WONE:

14 **Q. So in paragraph -- I'm sorry, on**
15 **page 11 of your expert report --**

16 A. Yes.

17 **Q. -- Exhibit MK1, you mentioned**
18 **that the -- you believed the data from the Madison**
19 **Memory Study should be analyzed as a whole,**
20 **correct?**

21 A. Yeah, it should be looked at as
22 a whole, yes.

23 **Q. And what did you mean by that?**

24 A. What I mean is that in the
25 context of my report that the statistical

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1 comparisons are important, but it's also important
2 to look at trends. And as I said before, I think
3 that trends are extremely important. And many of
4 my colleagues who do human studies with dietary
5 substances agree that trends are important to
6 report because we often don't have the statistical
7 power to -- you know, we don't -- we don't have,
8 you know, the ability to recruit a thousand people
9 or 500 people. And so it's very, very difficult
10 also with all of the factors that influence and
11 cause variability between people. It's very
12 difficult for us to get statistical -- to
13 statistically significant results. Everything is
14 stacked against us. There's an enormous amount of
15 variability that humans have that we don't have
16 with animal experiments. And because we don't
17 even know what some of the factors are
18 contributing to variability, we can't control for
19 them.

20 So because of that, I think it's
21 very important to not just very narrowly and very
22 strictly look at the p-values, but also to look at
23 trends. And I don't know if you have any of my
24 papers pulled up, but I have many papers where I
25 talk about trends and I report them. So that's

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1 what I meant by looking at the data as a whole.

2 Look at the statistical
3 analysis, yes, it's important. No question about
4 it. But it's also important to see that the
5 trends that are observed are unlikely to occur
6 randomly.

7 **Q. Let's talk about the Madison**
8 **Memory Study. Did you look at the entire**
9 **population of the Madison Memory Study?**

10 MS. METZINGER: Objection to
11 form.

12 MR. WONE: I'll correct it.

13 BY MR. WONE:

14 **Q. Did you analyze the data for the**
15 **entire population of the Madison Memory Study?**

16 MS. METZINGER: Objection to
17 form.

18 THE WITNESS: I don't believe
19 that I did. I focused on the
20 manuscript, so I don't -- I don't --
21 that they reported on that.

22 BY MR. WONE:

23 **Q. Now, when you look at the entire**
24 **population in the Madison Memory Study, was there**
25 **statistically significant results between group on**

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1 **any of the measures?**

2 A. Can you point me to the paper
3 where that would be and I'll -- I'll look at it
4 more closely?

5 MS. METZINGER: I'll just note
6 my objection to the form of that
7 question as well.

8 BY MR. WONE:

9 **Q. So if you go to Exhibit MK3.**

10 A. MK3, mm-hmm.

11 **Q. And turn to page 5. And I'm**
12 **referring to the page numbers on the bottom**
13 **corners of the document.**

14 A. Yep.

15 **Q. First line of the result**
16 **section.**

17 A. Okay. Mm-hmm. I see that.

18 **Q. Do you understand that to --**

19 A. They did do -- they did do an
20 analysis of the entire population.

21 **Q. And do you agree that there were**
22 **no statistically significant results for the**
23 **entire population?**

24 MS. METZINGER: Objection to
25 form.

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1 A. I don't know if the improvement
2 is clinically significant, but I do believe that
3 the effect size is -- is a medium to high effect
4 size when you look at the effect size. But -- but
5 I do not know whether or not -- what the level of
6 clinical significance of these differences are.

7 **Q. Could a medium to high effect**
8 **size still be clinically -- not clinically**
9 **significant?**

10 MS. METZINGER: Objection to
11 form.

12 THE WITNESS: That's a hard
13 question to ask, Mr. Wone -- to answer,
14 Mr. Wone. I think it depends on the
15 situation.

16 BY MR. WONE:

17 **Q. I'm talking about the situation**
18 **specifically in the Madison Memory Study.**

19 A. It is possible. It is possible
20 that statically significant results are not
21 clinically significant.

22 **Q. Okay. Further down in**
23 **paragraph 33, last full sentence starting with**
24 **within the AD8 0-1 group --**

25 A. Yes.

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1 THE WITNESS: I don't see the
2 data. I believe their sentence. I
3 believe their statement, but I don't
4 see the data, so I couldn't comment on
5 it.

6 BY MR. WONE:

7 **Q. You don't have any reason to**
8 **disagree with what's written in that sentence --**

9 A. That's correct. That's correct.

10 **Q. Okay. If we could go back to**
11 **your expert reports, Exhibit MK1. If you could go**
12 **to paragraph 33.**

13 A. Okay.

14 **Q. Kind of in the middle of the**
15 **paragraph where you're discussing the results of**
16 **the AD8 0-2 group, you use the phrase**
17 **"significantly more."**

18 **Do you see that?**

19 A. Yes.

20 **Q. And when you said "significantly**
21 **more," what kind of significance did you mean?**

22 A. I meant statistically
23 significantly more.

24 **Q. Do you know whether the**
25 **improvement was clinically significant?**

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1 **Q. -- you again use the phrase**
2 **"significantly more."**

3 **Do you see that?**

4 A. Yes.

5 **Q. And were you referring to**
6 **statistical significance in this --**

7 A. Yes.

8 **Q. -- sentence?**

9 A. Yes.

10 **Q. Do you know whether the**
11 **improvement you mentioned in this sentence in**
12 **paragraph -- the last sentence of paragraph 33 was**
13 **clinically significant?**

14 A. I can't comment on that.

15 **Q. Do you know whether any of the**
16 **measures in the AD8 0-2 group that were**
17 **statistically significant measured memory?**

18 A. Okay. So it was the -- so the
19 three tests that were statically significant were
20 tests that measured executive function, attention,
21 and visual learning. Visual learning certainly
22 requires memory. Right? You can't learn
23 something unless you can remember it. It requires
24 memory. So memory is connected with visual
25 learning.

<p style="text-align: right;">201</p> <p>1 In addition, executive function, 2 your ability to -- to organize your thoughts 3 and -- requires that you can remember things. 4 Otherwise, you cannot organize them. 5 So the statistically significant 6 ones were not tests that focused on memory as a 7 primary outcome, but they certainly require good 8 memory in order to be good on those tests. 9 And the -- there are a couple of 10 other tests that do specifically point -- are 11 specifically said to test memory itself, which are 12 the delayed recall tests, and -- and those tests, 13 I believe, showed a trend towards being effective. 14 Q. Did any of the measures in the 15 AD8 0-2 group that focus on memory specifically 16 have statically significant results? 17 A. No. 18 MS. METZINGER: Objection to 19 form. 20 BY MR. WONE: 21 Q. So even though none of the 22 measures for the 0-8 group -- 0 -- sorry. 23 Even though none of the measures 24 for the 0-2 group that had memory as a specific -- 25 as a specific outcome was statically significant,</p>	<p style="text-align: right;">203</p> <p>1 a -- a test given to humans related to 2 brain function. It's very rare that 3 you'd ever see one. All of the 4 different tests that are -- that are 5 used and have been validated and are 6 used in research studies have multiple 7 aspects of them, whether it's a 8 subjecting survey that's given or tests 9 like this. You have to give a battery 10 to capture the result because any -- 11 the result of any one is not nearly as 12 meaningful as the overall result of all 13 of them. 14 And because three out of nine 15 showed statistically significant 16 effects in the direction of a benefit 17 for apoeaquorin and then five 18 additional tests showed a trend in the 19 direction of benefit, my interpretation 20 of that is that that is extremely 21 unlikely to happen by chance, that if 22 everything were random, you'd expect to 23 see not only five tests that show no 24 results, but you'd accept -- you'd 25 expect to see as many tests showing the</p>
<p style="text-align: right;">202</p> <p>1 you would still conclude that Prevagen has 2 improved memory? 3 A. Yes. 4 MS. METZINGER: Objection to 5 form. 6 THE WITNESS: Yes, I would. And 7 the -- and the reason, Mr. Wone, is a 8 couple of things. One is that there's 9 a reason why a battery of tests is 10 being done. There's a reason why they 11 don't just do one test because they 12 need to capture as many aspects of 13 memory and cognitive function as 14 possible. So they do these battery of 15 tests. And, in fact, some of them 16 supposedly focus on the same thing. So 17 there are a few that focus on memory. 18 But that's why you do a battery 19 of tests, because no one test in itself 20 is going to tell you whether or not -- 21 whether or not memory is affected. You 22 have to look at all of them. That's 23 why they do batteries of tests. 24 You know, you will never see 25 something related to brain function,</p>	<p style="text-align: right;">204</p> <p>1 placebo is better than apoeaquorin as 2 you see showing that apoeaquorin is 3 better than the placebo, and you just 4 don't in these data. The data as a 5 whole then you look at it is pointing 6 in the direction of a benefit 7 statically and also via trends. 8 BY MR. WONE: 9 Q. I'm sorry. What was the last 10 word you said? Via? 11 A. Statically and also by looking 12 at trends. Looking at the statistics and the 13 trends together for all nine of these tests, to me 14 the conclusion I reach is that there is a benefit. 15 Q. You've mentioned trends, so why 16 don't we return to a page in your report where we 17 discuss that further. If you could turn to 18 page 11, paragraph 50, please. 19 A. Yes. 20 Q. And in this section, you state 21 that conclusions should be drawn logically? 22 A. Mm-hmm. 23 Q. What did you mean by that? 24 A. Well, by logic, what I mean is 25 what I was talking about before, that there's a</p>

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1 certain amount of common sense and logic that
2 needs to be applied in the context of statistical
3 analysis.

4 It's very easy for statisticians
5 to get caught up with numbers and to forget the
6 bigger picture of what they're looking at, and all
7 they care about is the p-value and the corrections
8 and that's where they stop. And they may not have
9 any knowledge of the biology at all. They may
10 completely not know anything about biology. All
11 they know is mathematics and -- and that's where
12 their knowledge ends.

13 What I mean by logic or common
14 sense is that, as I said -- and this could even
15 potentially be a statistical point, is that when
16 you look at table 1, which is on the next page,
17 and you see the nine tests and you see that --
18 that three of them show a statistical benefit in
19 the direction of effectiveness, one of them shows
20 exactly the same effect, so there's no -- no
21 difference. And the other five show the direction
22 of the difference is in direction of benefit of
23 apoeaquorin.

24 And what I mean by logic is that
25 is very unlikely to have happened by chance, that

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1 if you were expecting the effects to be totally
2 random, that if you see three statically
3 significant results in the direction of benefit of
4 apoeaquorin, you ought to see three statistically
5 significant effects in the direction of benefit of
6 the placebo. That would be random. And the
7 trends should also be showing trends in both
8 directions. That would be random.

9 If what you see is statistical
10 significance with a few of these and most of the
11 others show the direction of a benefit, my
12 interpretation of this, and this is using my
13 logic, not using a statistical analysis, it's
14 using other parts of my brain to understand this,
15 is that the totality of the data here point very
16 clearly in the direction of a benefit.

17 **Q. Are there standards that experts**
18 **in your field use to draw conclusions logically?**

19 MS. METZINGER: Objection to
20 form.

21 MR. de LEEUW: Objection to
22 form.

23 THE WITNESS: No, there aren't
24 and standards for logic. And I would
25 say that -- but I would say that many,

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1 many of my colleagues would agree with
2 me about this. Many colleagues who
3 work in nutrition, who work in the
4 fields -- some field related to dietary
5 supplements who would look at this
6 would agree that trends are very, very
7 important, people who do human
8 experimentation and understand the
9 variability. Particularly, researchers
10 who are looking at very, very low risk
11 substances, the trends would be
12 extremely important.

13 So I don't think that there is a
14 standard. But, in my view, the fact
15 that there isn't a standard doesn't
16 mean that it's not right.

17 BY MR. WONE:

18 **Q. And so it's possible that**
19 **another expert in your field could draw a**
20 **different conclusion even though both of you are**
21 **looking at something logically?**

22 MS. METZINGER: Objection to
23 form.

24 THE WITNESS: Anything is
25 possible.

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1 BY MR. WONE:

2 **Q. Okay. In paragraph 50, you also**
3 **use the phrase, and we've -- you've used it**
4 **earlier today, "nonsignificant trend towards**
5 **efficacy."**

6 A. Yes.

7 **Q. Do you see that?**

8 A. Yes.

9 **Q. And when does something trend**
10 **towards efficacy?**

11 A. The trend reflects the direction
12 of the absolute changes. And, you know, I will
13 say that I know that one of the -- one of the
14 statistical experts, FTC experts, said it's not
15 statically significant, end of story, you don't
16 even talk about it. And I disagree with that very
17 strongly.

18 I -- I certainly feel, and I
19 teach my students this all the time because they
20 make the mistake of saying simply this -- the
21 treatment differs from the placebo because the
22 absolute number is different without clarifying
23 that they're not -- they are actually not
24 statically significant. So that's true, in a
25 statistical sense they're not different. But --

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1 and so you should never ever say that they're just
2 flat-out that they're different if it's only the
3 absolute differences.

4 But you certainly can say, and
5 it's perfectly permissible to say, there is a
6 difference, but it's not statistically significant
7 especially when in the context of what we're
8 talking about here, which is a number that are all
9 trending in the same direction. That's when
10 trends really interest me.

11 If it's just a one-off thing
12 that is a trend, I probably wouldn't comment on
13 it. If one of them was going in the direction of
14 benefit, I wouldn't have valued that very much.
15 But when almost all of them do, to me, that's
16 where I say we got to look at this and take
17 this -- take this, you know, as important -- an
18 important result.

19 **Q. And would even a small amount of**
20 **improvement in the direct -- sorry.**

21 **Would even a small increase**
22 **towards the direction of improvement mean that**
23 **something trend towards efficacy?**

24 MS. METZINGER: Objection to
25 form.

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1 THE WITNESS: Yes, I think that
2 it does in the context of having nine
3 tests here. So you have to keep
4 remembering context that we're talking
5 about. You know, if there was one
6 small change in the direction of
7 efficacy in -- in a large group, I
8 would not say that that's important.
9 But the fact that five out of nine of
10 these or -- or let's say there were
11 three significant results and five out
12 of six of the other results go in the
13 direction of efficacy, as I said
14 before, I hate to keep repeating
15 myself, it is unlikely to be random, a
16 random effect.

17 So in the context of all of
18 these tests being done, I would make
19 that statement. But I would not
20 necessarily make that statement about
21 one result. I wouldn't look at one
22 result necessarily and say it's
23 trending in a certain direction. But
24 because it's a group of results, then
25 it becomes more interesting.

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1 BY MR. WONE:

2 **Q. You used the expression earlier**
3 **that something cannot -- that it can't be**
4 **explained by chance. So I'd like to I guess**
5 **understand, when you say it can't be explained by**
6 **chance, what do you mean?**

7 A. What I -- what I said was that
8 it's very unlikely to be explained by chance. And
9 what I mean by that is if you have -- if you have
10 eight tests that you're giving, that randomness,
11 if the effects are entirely random, you would not
12 expect to see any kind of pattern. You'd expect
13 to see results going in every direction. And that
14 would -- that is what randomness means. It means
15 there is equal probability of the result going in
16 one direction as there is of the result going in
17 the other direction. And so because of that, you
18 should see the results going in both directions.
19 But -- and that's what I mean by -- by unlikely to
20 be explained by chance.

21 **Q. And so if you don't see the**
22 **results going in both directions, you believe it's**
23 **unlikely, but it's not impossible that it's -- it**
24 **could still be related to chance, correct?**

25 MS. METZINGER: Objection to

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1 form.

2 THE WITNESS: Well, Mr. Wone, it
3 could be related -- it could be a
4 result of chance in the same way that
5 even if you get a p-value of .05, it's
6 possible that that really was a result
7 of chance too. As I said, anything is
8 possible when you're talking in the --
9 in the world of hypotheticals. But
10 it's very, very unlikely, which I think
11 is a more relevant -- a more relevant
12 approach to this than -- than using
13 whether it's possible or not.

14 BY MR. WONE:

15 **Q. And in the -- in the Madison**
16 **Memory Study when you describe measures as**
17 **trending towards efficacy, do you know whether**
18 **those improvements were clinically significant?**

19 A. I do not. I cannot -- I cannot
20 answer regarding clinical significance.

21 **Q. Well, let's look at one of your**
22 **tables. If you could turn to page 12, table 1.**
23 **Do you see that, Doctor?**

24 A. Yes, I do.

25 And I apologize if you can hear

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1 the lawn mower in the background. They'll be gone
2 in a couple of minutes.

3 **Q. I cannot, so --**

4 **A. Okay. Good.**

5 **Q. -- we're fine.**

6 **And so in the second column,**
7 **when you say "Direction of Improvement, Increase"**
8 **or "Decrease," what did you -- how did you decide**
9 **whether to put increase or decrease?**

10 **A. The direction of improvement in**
11 **this particular -- in this particular column**
12 **refers to the direction -- some of these tests, if**
13 **you -- if the -- if the number goes down, it's a**
14 **good thing. And others of the tests, if the**
15 **number goes up, it's a good thing. So that's what**
16 **this is saying, that with the ISL and the ISRL, if**
17 **the numbers increase, that shows improvement.**
18 **With the GML and the GMR, if the numbers decrease,**
19 **that shows improvement. So that's what that**
20 **column is referring to.**

21 **Q. Okay.**

22 **A. I'm sorry if it wasn't clear.**

23 **Q. And so for the last two, ONB, a**
24 **decrease means that if the number went down, that**
25 **would be an improvement?**

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1 **A. That's correct.**

2 **Q. So I'd like to introduce what's**
3 **been marked as Exhibit MK9.**
4 **(Marked Exhibit MK9.)**

5 **THE WITNESS: Okay.**

6 **BY MR. WONE:**

7 **Q. Do you see that, Doctor?**

8 **A. Yes.**

9 **Q. Okay. And just to, I guess, go**
10 **back. When you said in your report in table 1,**
11 **ONB, what measure was ONB?**

12 **A. They -- I think the one -- the**
13 **one card back. Is that the one that it is?**

14 **Q. Okay. And do you know what TWOB**
15 **was?**

16 **A. The two card back.**

17 **Q. And if you could go to -- back**
18 **to Exhibit MK9 and turn to page 4.**

19 **A. Okay.**

20 **Q. Do you see the -- under the task**
21 **name "One Back"?**

22 **A. Yes.**

23 **Q. And do you see the fourth column**
24 **under description?**

25 **A. Yes.**

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1 **Q. And what does under**
2 **description -- under description, what does the**
3 **document say a higher score means on the One Back?**

4 **A. Higher score is better**
5 **performance.**

6 **Q. Going back to your report in**
7 **Exhibit MK1, what did you write in the direction**
8 **of improvement for the One Back?**

9 **A. I wrote decrease.**

10 **Q. And so does the document I've**
11 **shown you in Exhibit MK9 change your opinion about**
12 **whether a decrease or increase is the direction of**
13 **improvement?**

14 **MS. METZINGER: Objection to**
15 **form.**

16 **THE WITNESS: Hang on one**
17 **second.**

18 **It looks like that's correct.**

19 **It looks like that there's an error**
20 **somewhere because this does not agree**
21 **with what I had in my report. And I**
22 **did not have access to this Cogstate**
23 **document when I was writing my report.**
24 **I've not seen this Cogstate document**
25 **before. And so I was using other**

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1 documents in order to -- to determine
2 which direction the benefit or
3 effectiveness would be shown. But it
4 looks as though you're correct, that
5 the One Back test -- in the One Back
6 test, the Cogstate document says that a
7 higher score is better performance.

8 **BY MR. WONE:**

9 **Q. Okay.**

10 **A. And in my document, I wrote that**
11 **a lower score is better -- is better performance.**
12 **So there does seem to be some kind of error**
13 **between the two.**

14 **Q. And so when you report in table**
15 **1, the direction of improvement for the One Back**
16 **should be increase, not decrease?**

17 **A. Yeah, if the Cogstate document**
18 **is correct, then you're right, it should be**
19 **increase rather than decrease.**

20 **I would want to see the -- not**
21 **just the Cogstate document -- which, of course, is**
22 **probably correct. I don't doubt that. But I**
23 **would want to look at some of the other sources I**
24 **had to try to see why I put decrease and see if**
25 **it's possible that there's some other kind of**

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1 error.

2 But assuming that the Cogstate
3 document is correct, then you're right, that's --
4 that's a mistake.

5 **Q. And assuming that the Cogstate**
6 **document is correct, does it also mean that in**
7 **table 1 the -- when you change increase --**
8 **decrease to increase, that the placebo**
9 **outperformed the treatment group on the One Back?**

10 A. That's correct.

11 MS. METZINGER: Objection to
12 form.

13 BY MR. WONE:

14 **Q. And is it also correct to say**
15 **that instead of "effective" in the last column on**
16 **the right, it should say "placebo better"?**

17 A. Yes.

18 MS. METZINGER: Objection to
19 form.

20 BY MR. WONE:

21 **Q. I'd like to go back to**
22 **Exhibit MK9. If you could go back to page 4 and**
23 **look at the task for Two Back. Do you see that,**
24 **Doctor?**

25 A. I do.

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1 **Q. And do you see what the**
2 **description column says for the Two Back regarding**
3 **higher score?**

4 A. Yes. Higher score, better
5 performance.

6 **Q. And what did you say -- Two Back**
7 **in table 1 of your report in Exhibit MK1?**

8 MS. METZINGER: Eric, your audio
9 cut out for that question.

10 MR. WONE: Sure.

11 BY MR. WONE:

12 **Q. What did you say the direction**
13 **of improvement should be in table 1 of your expert**
14 **report --**

15 A. The same thing as --

16 **Q. -- for the Two Back?**

17 A. -- the other, decrease. And it
18 looks as though it should actually be increase if
19 the Cogstate report is correct.

20 **Q. And if the direction improvement**
21 **for the Two Back should be increase, does that**
22 **mean that the placebo group outperformed the**
23 **treatment group?**

24 MS. METZINGER: Objection to
25 form.

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1 THE WITNESS: I would say that
2 the trend would be in that direction.

3 BY MR. WONE:

4 **Q. And so the trend should say,**
5 **instead of "effective" for the Two Back in table**
6 **1, it should say "placebo better," correct?**

7 A. Yes.

8 MS. METZINGER: Objection to
9 form.

10 BY MR. WONE:

11 **Q. And going on to table 2 of your**
12 **expert report, which is on page 13, should the**
13 **direction of improvement for the One Back in**
14 **table 2 also say "increase"?**

15 MS. METZINGER: Objection to
16 form.

17 THE WITNESS: Yes.

18 BY MR. WONE:

19 **Q. And with that change to say**
20 **"increase," did the placebo group outperform the**
21 **treatment group on the One Back measure in**
22 **table 2?**

23 A. Yes.

24 MS. METZINGER: Objection to
25 form.

220

1 BY MR. WONE:

2 **Q. And so instead of "effective,"**
3 **it should say "placebo better" in the trend column**
4 **for the One Back, correct?**

5 A. Correct.

6 MS. METZINGER: Objection to
7 form.

8 BY MR. WONE:

9 **Q. And how about the Two Back in**
10 **table 2? Instead of "decrease," should it also**
11 **say "increase"?**

12 MS. METZINGER: Objection to --

13 THE WITNESS: Yes.

14 MS. METZINGER: -- form.

15 BY MR. WONE:

16 **Q. What was your answer, Doctor?**

17 A. Yes.

18 **Q. And with that change to**
19 **increase, did the placebo group outperform the**
20 **treatment group on the Two Back in table 2?**

21 MS. METZINGER: Objection to
22 form.

23 THE WITNESS: Yes.

24 BY MR. WONE:

25 **Q. And should the trend for the Two**

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1 **Back in table 2 say "placebo better" instead of**
2 **"effective"?**

3 A. Yes.

4 MS. METZINGER: Objection to
5 form.

6 BY MR. WONE:

7 **Q. So with these changes to**
8 **table 2, how many measures trend towards placebo?**

9 MS. METZINGER: Objection to
10 form.

11 THE WITNESS: In table 2, which
12 is the 0-1 group, which is not the
13 exact group of interest, then what we
14 find is that three of the endpoints
15 are -- show statically significant
16 effectiveness. And of the other six,
17 three of them, the trend -- I would --
18 I would say that the trends are not --
19 don't -- are not helpful in -- because
20 they cancel each other out.

21 So there were -- in the trends,
22 there were three that go in the
23 direction of apoeaquorin effectiveness
24 and there are three that go in the
25 direction of the placebo being better.

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1 you --

2 THE WITNESS: I'm sorry.

3 MS. METZINGER: Thank you. You
4 can go ahead.

5 BY MR. WONE:

6 **Q. What was your response to my**
7 **question, Doctor?**

8 A. That's correct, in the 0-1
9 group, if what you're saying is correct, that the
10 One Back and Two Back should be increased in the
11 direction of improvement, then there are three
12 tests that show statically significant benefit of
13 apoeaquorin. And of the six other tests that do
14 not show statistical significance, two are
15 trending in the direction of effectiveness of
16 apoeaquorin and four are trending in the direction
17 of the placebo being better.

18 **Q. So if -- if five measures**
19 **overall trend toward treatment and four measures**
20 **trend towards placebo, would you agree that that**
21 **is close to what you would expect for a random**
22 **effect?**

23 MS. METZINGER: Objection to
24 form and mischaracterizes the witness'
25 testimony.

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1 But that doesn't take away from the
2 fact that the only statistically
3 significant effects that were seen are
4 three in the direction of -- of
5 apoeaquorin.

6 BY MR. WONE:

7 **Q. Wouldn't there be four measures**
8 **that are placebo better?**

9 A. Oh, I'm --

10 **Q. One --**

11 A. -- sorry.

12 **Q. -- Back --**

13 A. Right.

14 **Q. One Back, Two Back --**

15 A. Ah --

16 **Q. -- ISLR --**

17 A. -- yes.

18 **Q. -- and the --**

19 A. Yes.

20 **Q. -- IDN?**

21 A. Yes, that's right. And the --

22 MS. METZINGER: Objection to
23 form.

24 Dr. Kurzer, just give me a
25 moment to state my objection before

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1 THE WITNESS: In this case, with
2 this table, I think the fact that we
3 find three to be statically significant
4 in the direction of efficacy and we
5 find none to be statically significant
6 in the direction of the placebo being
7 better, it still provides evidence
8 providing towards efficacy of -- of
9 apoeaquorin.

10 And if you look at the A
11 through 2 group on the previous table,
12 table 1, I think it's even more the --
13 what I just said is even more apparent
14 because there are only what -- in table
15 1, when we look at the 0-2, which in my
16 view, my interpretation of the methods
17 and the protocol is that this is the
18 group of interest, that there are three
19 tests that show statistical
20 significance in the direction of
21 effectiveness, that show statistically
22 significant effectiveness, that there's
23 one that shows no difference, that
24 there are two that show a trend towards
25 the placebo being better, and there are

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1 then three that show a trend towards
2 the apoeaquorin being better.

3 So this table 1 is more relevant
4 than table 2, although I think they
5 both provide evidence that apoeaquorin
6 is effective. I think table 1 is more
7 relevant and the data are a little bit
8 stronger.

9 BY MR. WONE:

10 **Q. Are participants in the AD8 0-1**
11 **group healthy older adults?**

12 A. Yes, in my opinion they are.

13 **Q. And it's your opinion that**
14 **Prevagen is intended for healthier older adults?**

15 A. Yes.

16 MS. METZINGER: Objection to
17 form.

18 BY MR. WONE:

19 **Q. If we could go to paragraph 52**
20 **of your report --**

21 A. Mm-hmm.

22 **Q. -- Exhibit MK1.**

23 A. Yes, I'm here.

24 **Q. In your second to last sentence,**
25 **you say that the -- starting with "As is true," do**

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1 **you see that sentence?**

2 A. Yes, I do.

3 **Q. You use the phrase "strongly**
4 **suggestive of a benefit of treatment."**

5 **What did you mean by "strongly**
6 **suggestive"?**

7 A. What I mean is that the data
8 suggests a benefit of treatment. And the word
9 "strongly" is meant to sort of emphasize that a
10 little bit.

11 **Q. And given the changes we've**
12 **discussed, is it still your opinion that the data**
13 **is strongly suggestive of a benefit of treatment?**

14 MS. METZINGER: Objection.

15 THE WITNESS: I would
16 probably --

17 MS. METZINGER: Go ahead. Thank
18 you.

19 THE WITNESS: I would probably
20 take out the word "strongly" and I
21 would say it is suggestive of a
22 benefit. I still believe that
23 table 1 -- that table 2, excuse me, is
24 suggestive of a benefit, although not
25 as strongly as table 1.

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1 BY MR. WONE:

2 **Q. And when something is suggestive**
3 **of a benefit, does that mean it's not proven?**

4 MS. METZINGER: Objection to
5 form.

6 THE WITNESS: To me, the word
7 "proven" is not a very useful word
8 because in science, as you well know
9 with -- there is a -- a spectrum of
10 proof, and you have to decide what your
11 threshold is for accepting that
12 evidence. It's very hard to say that
13 anything is proven in the sense that --
14 you know, that absolutely a hundred
15 percent. It's really what is the
16 threshold of evidence. And in this
17 case, I would say that the threshold is
18 met for it to be -- for there to be a
19 benefit from apoeaquorin.

20 BY MR. WONE:

21 **Q. So if I'm understanding you**
22 **correctly, you believe the threshold for showing a**
23 **benefit of apoeaquorin is met when the data is**
24 **suggestive?**

25 MS. METZINGER: Objection to

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1 form.

2 THE WITNESS: I think that the
3 word "suggestive," you're interpreting
4 it as meaning -- you're interpreting it
5 a little bit differently than me. I'm
6 using the word "suggestive" because we
7 haven't proven statistical significance
8 for all of the endpoints, and so I'm
9 using that word to soften my conclusion
10 a little bit. But I could have written
11 it differently and said it is
12 suggestive of a benefit of treatment,
13 but I wanted to acknowledge that there
14 were some results that did not
15 statically show benefit.

16 BY MR. WONE:

17 **Q. And you also don't know whether**
18 **the benefits that you saw were clinically**
19 **significant?**

20 A. That's correct.

21 MS. METZINGER: Objection.
22 Asked and answered.

23 MR. WONE: Can we go off the
24 record for a moment?

25 MS. METZINGER: Sure.

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1 THE VIDEOGRAPHER: We are going
2 off the record at 2:36 P.M.
3 (Off the record from 2:36 until
4 3:07.)

5 THE VIDEOGRAPHER: We are going
6 back on the record at 3:07 P.M.

7 BY MR. WONE:

8 **Q. Dr. Kurzer, if you could go back**
9 **to your expert report, Exhibit MK1, please, and**
10 **turn to paragraph 47.**

11 A. Okay.

12 **Q. In that paragraph, do you see an**
13 **article by Eichstaedt cited?**

14 A. Yes.

15 **Q. Hold on a second. Sorry.**

16 **Okay. I'm introducing what has**
17 **been mark as Exhibit MK10.**

18 **(Marked Exhibit MK10.)**

19 BY MR. WONE:

20 **Q. Do you see that, Dr. Kurzer?**

21 A. I do.

22 **Q. And is this the Eichstaedt**
23 **article that you cited in your expert report?**

24 A. I assume that it is because
25 you're telling me so. So, you know, it is --

230

1 Eichstaedt is the first author, so I assume that
2 that's correct, yes.

3 **Q. In this article, Eichstaedt**
4 **discusses an alternative to Bonferroni --**

5 A. Mm-hmm.

6 **Q. -- correct?**

7 A. Yes.

8 **Q. And what was the alternative**
9 **that Eichstaedt mentioned?**

10 A. It's a different type of -- of
11 correction called "The Holm's sequential
12 Bonferroni procedure."

13 **Q. And do you agree that Eichstaedt**
14 **believes that Holm is better because it protects**
15 **against heightened type 1 error without**
16 **increasing -- unnecessarily increasing type 2**
17 **error?**

18 MS. METZINGER: Objection to
19 form.

20 THE WITNESS: I believe that
21 that's what they are saying.

22 BY MR. WONE:

23 **Q. And was Eichstaedt recommending**
24 **use of the Holm correction in -- in**
25 **neuropsychological studies?**

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1 A. They're saying that it may be a
2 better test than the Bonferroni.

3 **Q. Do you believe that Holm would**
4 **be an appropriate correction to apply in the**
5 **Madison Memory Study?**

6 A. I can't answer that from just
7 seeing one paper making this suggestion. My
8 reason for citing this was just to add to the
9 literature showing that there isn't necessarily a
10 consensus among statisticians. But I haven't seen
11 the Holm's sequential Bonferroni applied to these
12 data and so I can't comment on if it would be
13 appropriate or not.

14 It may be that it's -- that
15 it's -- that it turns out to be overly strict just
16 as Bonferroni is, although they say that it -- it
17 doesn't cause an increased type 2 error rate. I
18 would need to really see it done to be able to see
19 that.

20 **Q. Have you ever used the Holm**
21 **Bonferroni in any of your research?**

22 A. I have not.

23 **Q. Do you have any other**
24 **experiences with the Holm Bonferroni correction?**

25 A. I do not.

232

1 **Q. I'd like to introduce what's**
2 **been marked as Exhibit MK11.**

3 **(Marked Exhibit MK11.)**

4 BY MR. WONE:

5 **Q. Do you see that, Dr. Kurzer?**

6 A. I do.

7 **Q. Do you recognize the document in**
8 **Exhibit MK11, Doctor?**

9 A. No, I don't.

10 **Q. For the Madison Memory Study,**
11 **have you ever seen data for any of the AD8 groups**
12 **listed in Exhibit MK11?**

13 MS. METZINGER: Objection to
14 form.

15 THE WITNESS: The manuscript
16 shows the 0-1 and the 0-2. And then I
17 think we also saw the 3-5. I don't
18 recall seeing the other data.

19 BY MR. WONE:

20 **Q. How about outside of the**
21 **manuscript? Have you seen any of the other AD8**
22 **groups besides the ones you just mentioned?**

23 A. I don't recall. I don't recall
24 seeing them.

25 **Q.** [REDACTED]

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1 [REDACTED]
 2 [REDACTED]
 3 [REDACTED]
 4 MS. METZINGER: Objection to
 5 form.
 6 THE WITNESS: [REDACTED]
 7 [REDACTED]
 8 BY MR. WONE:
 9 Q. [REDACTED]
 10 [REDACTED]
 11 MS. METZINGER: Objection to
 12 form.
 13 THE WITNESS: [REDACTED]
 14 [REDACTED]
 15 BY MR. WONE:
 16 Q. [REDACTED]
 17 [REDACTED]
 18 [REDACTED]
 19 MS. METZINGER: Objection to
 20 form.
 21 THE WITNESS: [REDACTED]
 22 [REDACTED]
 23 BY MR. WONE:
 24 Q. Yes.
 25 MS. METZINGER: What was the

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1 THE WITNESS: [REDACTED]
 2 [REDACTED]
 3 [REDACTED]
 4 BY MR. WONE:
 5 Q. Do you know why the Madison
 6 Memory Study investigators would conduct all of
 7 the analyses in Exhibit MK11?
 8 MS. METZINGER: Objection to
 9 form. Mischaracterizes the document.
 10 THE WITNESS: So are you telling
 11 me that they did do all of these
 12 analyses? Is that what you're saying?
 13 BY MR. WONE:
 14 Q. Let's assume that they did. Do
 15 you know why the investigators for the Madison
 16 Memory Study would --
 17 MS. METZINGER: I'm going to --
 18 MR. WONE: -- analyses?
 19 MS. METZINGER: I'm going to
 20 object to that question, Mr. Wone. If
 21 you want to make that representation to
 22 her, fine. But I would object to that
 23 question both as to form and on the
 24 grounds that it's misleading.
 25

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1 question, Mr. Wone?
 2 (Reporter read back requested
 3 material.)
 4 MS. METZINGER: Objection to
 5 form.
 6 THE WITNESS: [REDACTED]
 7 [REDACTED]
 8 [REDACTED]
 9 BY MR. WONE:
 10 Q. [REDACTED]
 11 A. [REDACTED]
 12 [REDACTED]
 13 [REDACTED]
 14 Q. [REDACTED]
 15 [REDACTED]
 16 [REDACTED]
 17 [REDACTED]
 18 A. [REDACTED]
 19 Q. [REDACTED]
 20 A. [REDACTED]
 21 Q. [REDACTED]
 22 [REDACTED]
 23 [REDACTED]
 24 MS. METZINGER: Objection to
 25 form.

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1 BY MR. WONE:
 2 Q. I'm asking you to make the
 3 assumption that they -- that the Madison Memory
 4 Study researchers did.
 5 MS. METZINGER: And at what
 6 point in time?
 7 MR. WONE: I'm sorry?
 8 MS. METZINGER: At what point in
 9 time is Dr. Kurzer to assume that these
 10 analyses were conducted?
 11 MR. WONE: Assume that they were
 12 conducted after the Madison Memory
 13 Study had been completed.
 14 MS. METZINGER: Okay. And --
 15 and how about in comparison with other
 16 analyses that may have been run and
 17 before or after the data was looked at?
 18 MR. WONE: I'm not asking -- I'm
 19 not asking about other analyses. I'm
 20 asking about the ones in Exhibit MK11.
 21 MS. METZINGER: And if you
 22 can -- if you're asking her a
 23 hypothetical, I would appreciate you
 24 completing that hypothetical so that
 25 Dr. Kurzer is aware of exactly the

<p style="text-align: right;">237</p> <p>1 hypothetical that you're posing to her.</p> <p>2 MR. WONE: I'm asking Dr. Kurzer</p> <p>3 assuming that the Madison Memory Study</p> <p>4 investigators completed the analyses</p> <p>5 displayed in Exhibit MK11 after the</p> <p>6 study was completed, do you know why</p> <p>7 they would do that.</p> <p>8 MS. METZINGER: Are you saying</p> <p>9 after the study was completed but</p> <p>10 before any analyses were conducted?</p> <p>11 MR. WONE: At any point after</p> <p>12 the study was completed.</p> <p>13 MS. METZINGER: Okay. Well, I</p> <p>14 think those are two different</p> <p>15 scenarios.</p> <p>16 MR. WONE: That's the scenario</p> <p>17 I'm asking.</p> <p>18 BY MR. WONE:</p> <p>19 Q. Dr. Kurzer?</p> <p>20 MS. METZINGER: Well, I don't</p> <p>21 understand -- I don't understand the</p> <p>22 scenario you're asking. That's what</p> <p>23 I'm saying.</p> <p>24 MR. WONE: I'm asking if any --</p> <p>25 I'm asking -- saying assume that</p>	<p style="text-align: right;">239</p> <p>1 I'll respond to you with a</p> <p>2 hypothetical. I don't know why they</p> <p>3 did all of those analyses. I think</p> <p>4 that it's reasonable. They were very</p> <p>5 clear in the manuscripts and in the</p> <p>6 protocol that healthy people were their</p> <p>7 primary -- were their primary targeted</p> <p>8 population.</p> <p>9 It's possible that they --</p> <p>10 because they had people with more --</p> <p>11 with higher cognitive dysfunction that</p> <p>12 they did some exploratory analyses for</p> <p>13 the purposes of seeing if it would be</p> <p>14 interesting to further study</p> <p>15 apoeaquorin in people who have</p> <p>16 neurological dysfunction. That's a</p> <p>17 reasonable thing to do. They</p> <p>18 didn't publi- -- I'm not aware that</p> <p>19 they published these data, in which</p> <p>20 case they would have had to say --</p> <p>21 should have said this is -- was this</p> <p>22 was a post hoc analysis which was not</p> <p>23 part of our original hypothesis.</p> <p>24 But -- but it's very, very</p> <p>25 common to use a data set in order to</p>
<p style="text-align: right;">238</p> <p>1 base -- the analyses in Exhibit 11 in</p> <p>2 MK11 were completed -- were conducted</p> <p>3 after the study was completed, does</p> <p>4 Dr. Kurzer know why these subgroup</p> <p>5 analyses would be done.</p> <p>6 MS. METZINGER: Well, I'm going</p> <p>7 to continue to object on the fact that</p> <p>8 that's an incomplete hypothetical.</p> <p>9 But, Dr. Kurzer, if you</p> <p>10 understand the question and you have an</p> <p>11 opinion on that, you can go ahead and</p> <p>12 answer.</p> <p>13 THE WITNESS: Yes, I'll answer</p> <p>14 that.</p> <p>15 I think that, Mr. Wone, if you</p> <p>16 really want the answer to that, you</p> <p>17 need to ask the people who did the</p> <p>18 study why they did those analyses. It</p> <p>19 does make a difference whether it</p> <p>20 was -- whether they were done in the</p> <p>21 original -- with the original data set</p> <p>22 or whether they were done after</p> <p>23 publication of the -- of the papers.</p> <p>24 That all would make a difference.</p> <p>25 But, again, as a hypothetical,</p>	<p style="text-align: right;">240</p> <p>1 generate other hypotheses to get a</p> <p>2 feeling for what else you might want to</p> <p>3 study. You have all this data. Why</p> <p>4 not look at it and see what's going on.</p> <p>5 Maybe you'll get a clue. And that</p> <p>6 could help put you in a new direction.</p> <p>7 So I think that there are</p> <p>8 reasonable, acceptable reasons why they</p> <p>9 would have done those other analyses.</p> <p>10 BY MR. WONE:</p> <p>11 Q. Go back to your expert report,</p> <p>12 Exhibit MK1.</p> <p>13 A. Okay.</p> <p>14 Q. And go to page -- page 14,</p> <p>15 please.</p> <p>16 A. Okay.</p> <p>17 Q. In your report, you reached</p> <p>18 conclusions relating to vitamin D in cognitive</p> <p>19 function, correct?</p> <p>20 A. Yes.</p> <p>21 Q. Do you know when -- sorry.</p> <p>22 Does Prevagen contain vitamin D?</p> <p>23 A. Yes, it does, I believe.</p> <p>24 Q. And do you know when vitamin D</p> <p>25 first appeared in Prevagen?</p>

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MS. METZINGER: Objection to form.

THE WITNESS: I don't recall when it was added.

BY MR. WONE:

Q. If you could look at paragraph 17 of your report, does that refresh your recollection as to when vitamin D was added to Prevagen?

A. Yes. 2016.

Q. Was vitamin D in the Prevagen that was used during the Madison Memory Study?

A. I don't believe so.

Q. If you could go back to the vitamin D section which was page 14.

A. Page 14.

Q. Yes.

A. 15.

Okay. I'm here.

Q. Did any of the studies cited in your report involving vitamin D use Prevagen?

A. No, they did not.

Q. Did any of the vitamin D studies used cited in your report include apoaequorin?

A. No, they did not.

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Q. If you could look at paragraph 61. It's on the bottom of page 15. Do you see that, Doctor?

A. I do.

Q. And does this paragraph list studies that you believe show beneficial associations between vitamin D and brain structure?

A. Yes.

Q. And what did you mean by "beneficial associations"?

A. What I meant was that vitamin D helps preserve healthy brain structure.

Q. What was the word you said after "helps"?

A. "Preserve" healthy brain structure.

Q. When you say "healthy, helps preserve," could you explain what you mean?

A. What I mean is that these studies showed that people with vitamin D deficiency had brain changes that reflect atrophy of the brain so that vitamin D deficiency is harmful to the brain. So in order to preserve brain structure, health -- a healthy brain

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structure, you would want to make sure not to be vitamin D deficient -- deficient.

Q. And is brain structure different from cognitive function?

A. Brain structure contributes to cognitive function so that brain atrophy would -- is certainly likely to have a negative affect on cognitive function.

Q. Can something preserve brain structure but not have any effect on cognitive function?

MS. METZINGER: Objection to form.

THE WITNESS: I couldn't answer that.

BY MR. WONE:

Q. How come?

A. I don't know the answer to that. Are there things that -- you know, are there specific examples of things that preserve brain -- are good for the brain or preserve brain structure but don't affect cognitive function? I'm not aware of examples of that. There may be some, but I'm not aware of them.

Q. Does having beneficial

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associations mean that vitamin D causes cognitive improvement in humans?

MS. METZINGER: Objection to form.

THE WITNESS: These studies alone do not prove that vitamin D improves cognitive function. These studies I listed here as part, again, of the totality of evidence showing that vitamin D has an effect on the brain because that's important to understand when you look at the other studies that I refer to later.

So I'm not suggesting that -- you know, all I'm suggesting is what I say, there's a beneficial association between vitamin D and brain structure. And so what we -- we know that vitamin D has an effect on the brain. There's no question about that. That's what I'm trying to get across here.

BY MR. WONE:

Q. And you mentioned vitamin D deficient. Is the effect the same in people who are not vitamin D deficient?

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MS. METZINGER: Objection to form.

THE WITNESS: That I don't know because these five studies that I cite all use vitamin D deficient people. So I can't reach a conclusion about that question.

BY MR. WONE:

Q. Okay. If you could go to paragraph 63.

A. Mm-hmm.

Q. It's on the next -- on page 16 of your expert report.

A. Yes.

Q. And then in this paragraph you discuss cross-sectional studies; is that right?

A. That's right.

Q. And what is a cross-sectional study?

A. A cross-sectional study is a study that looks at one time point and evaluates the relationship in this context, the relationship between vitamin D levels in the people and cognitive function at one time point.

Q. And when you used the phrase

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causation, but there's an association between vitamin D levels and cognitive function particularly in the case of deficiency.

But in some of these studies, and I'd have to look at each study individually, the vitamin D levels may not -- may not have been deficiency. In other words, they may have done sort of a correlation where they look at the full spectrum of vitamin D levels and they see that the lower the vitamin D the poorer the cognition, and the higher the vitamin D the better the cognition.

Q. Do cross-sectional studies control for other factors that could influence the outcome?

MS. METZINGER: Objection to form.

THE WITNESS: In cross-sectional studies, most epidemiologists will control for as much as they can, so they will control for other factors that may affect cognitive function. For example, something like socioeconomic status would be something that might be controlled for in these studies. So they do control for

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"beneficial associations" in paragraph 63, what did you mean?

A. What I meant is that vitamin D helps that -- in the case of the enhanced study, low levels of vitamin D were significantly associated with increased risk of cognitive impairment. So vitamin D is negatively associated with cognitive function. Excuse me. Wait a second. I said that wrong. With cognitive impairment. Vitamin D levels are positively associated with cognitive function so that low levels of vitamin D are associated with lower cognitive function or more cognitive impairments.

Q. Lower levels of vitamin D are associated with cognitive impairment?

A. Yes.

Q. Is that what you said?

A. Yes.

Q. Does that mean -- do these studies show -- do these studies in paragraph 63 show that increasing vitamin D improves cognitive function?

A. These are associate -- studies of association. So basically what they're saying is that there's an association between -- it's not

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factors that might confound the results.

BY MR. WONE:

Q. Would they control for factors that could affect someone's vitamin D levels like diet?

A. They should. They should. They should account for -- for things that affect vitamin D, other things that affect vitamin D levels, yes. But, again, I'd have to look at these studies. And I would -- I would suggest that it's very likely that the high quality papers did control for things or they would not have passed peer review and they would not have been published.

So, for example, in paragraph C on page 17, you can see that they adjusted for age, race, sex, body mass index, and education. So they adjusted for things that are well known to affect either cognitive function or vitamin D levels.

Q. And that study in paragraph C involved people who are vitamin -- involved vitamin D deficiency, correct?

A. Yes, they particular -- in

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1 particular, they focused on people who are vitamin
2 D deficient.

3 **Q. Do any of the studies cited in**
4 **paragraph 63 show that vitamin D improves**
5 **cognitive function?**

6 MS. METZINGER: Objection to
7 form.

8 THE WITNESS: No. As I said,
9 this is an observational study which
10 shows association. So lower vitamin D
11 levels were associated with poorer
12 cognitive function.

13 BY MR. WONE:

14 **Q. Okay. If we could go to**
15 **paragraph 64, please.**

16 A. Okay.

17 **Q. And in paragraph 64, you discuss**
18 **studies that show beneficial associations between**
19 **higher vitamin D intake and cognitive function,**
20 **correct?**

21 A. Yes, intake rather than levels.

22 **Q. And what is the difference**
23 **between intake and levels?**

24 A. In a study in which they're
25 looking at the relationship or the association

250

1 between vitamin D levels and cognitive function,
2 they're taking blood and measuring the amount of
3 vitamin D in the blood. In the -- in the studies
4 in paragraph 64, they're not measuring the vitamin
5 D in the blood, they're measuring through
6 questionnaires vitamin D intake. And they showed
7 that a higher vitamin D intake was associated with
8 better cognitive function.

9 **Q. And is your -- when you said**
10 **"beneficial associations" in paragraph 64, did you**
11 **have a similar meaning as to when you said**
12 **"beneficial associations" in your prior paragraphs**
13 **in this section?**

14 A. Yes. What I meant was that
15 higher vitamin D intake is associated with better
16 cognitive functioning. Lower vitamin D intake is
17 associated with poorer cognitive function.

18 **Q. And do any of the studies in**
19 **paragraph 64 show that vitamin D -- increasing**
20 **vitamin D improves cognitive function?**

21 A. They show association, not
22 causation.

23 **Q. Do any of the studies cited in**
24 **paragraph 64 show that vitamin D -- increases in**
25 **vitamin D causes improvement in memory?**

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1 A. I'd have to look at the studies
2 again to be reminded of exactly which cognitive
3 function tests that they did. In this -- for this
4 review of the literature, I looked at many aspects
5 of cognitive function, so it's very likely that
6 memory was -- was part of what they were -- what
7 they were evaluating.

8 **Q. When I asked about cognitive**
9 **function, you said that the studies in**
10 **paragraph 64 did not show causation, they**
11 **showed --**

12 A. Right.

13 **Q. -- association.**

14 A. That's right. They don't show
15 causation, the show association. That's correct.

16 **Q. And so -- and so I -- my second**
17 **question was, do any of the studies in**
18 **paragraph 64 show causation in terms of improving**
19 **memory or is it just association?**

20 A. Again, my response would be that
21 they don't show causation. I wouldn't say just
22 association because I think association is
23 important. I think that these studies are
24 important as part of the totality of the data.
25 Otherwise, they wouldn't be published if they were

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1 meaningless. So I think that the data are
2 important and significant, but they do not show
3 causation. I agree with you on that.

4 **Q. All right. If we could go to**
5 **paragraph 66. It's on page 21. Do you see that?**

6 A. Yes, I do.

7 **Q. And in this paragraph, in**
8 **paragraph 66 of Exhibit MK1, you mention -- you**
9 **used the phrase "prospective studies." Do you see**
10 **that?**

11 A. Yes.

12 **Q. And what is a prospective study?**

13 A. A prospective study is a study
14 in which you do your measurements before people --
15 you do your measurements at the point when, as far
16 as you know, everyone is healthy. And then you
17 follow them over some period of time either by
18 giving an intervention or by observing them to see
19 if there are groups of people who may have had --
20 experienced cognitive decline, and then you look
21 back and what their measurements were before they
22 became -- before their cognitive function
23 declined. And so these kinds of studies are
24 considered much -- to provide much stronger data
25 than the cross-sectional studies because it --

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1 they're not looking at one time point, they're
2 looking at a change over a long period of time.

3 **Q. And do you agree that the**
4 **studies you cited in paragraph 66 relate to**
5 **association not causation?**

6 MS. METZINGER: Objection to
7 form.

8 THE WITNESS: So this is -- this
9 is a little bit more nuanced, the
10 interpretation of these kinds of
11 studies. They are observational. They
12 are very, very strong observational
13 studies. They are the best kind of
14 epidemiological studies that can be
15 done. And although they -- the data
16 are not as strong as randomized
17 clinical trials in certain ways, in
18 other ways they're better because
19 clinical trials have limitations. And
20 I -- I know that the RCT is considered
21 the gold standard, but there is a great
22 disagreement about that.

23 There are epidemiologists who
24 will tear clinical trials to shreds
25 because of limitations in clinical

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1 trials. You have a smaller group. You
2 might not be capturing people who
3 respond to the drug. You're isolating
4 this and it's not in a real-world
5 situation.

6 So prospective studies like this
7 are looking at enormous numbers of
8 people in real-life situations, and
9 that is a tremendous strength above
10 that of a randomized clinical trial.
11 So the dogma is that prospective
12 study -- prospective epidemiological
13 studies don't show causation and
14 randomized clinical trials are
15 necessary to show causation, but they
16 both have strengths and they both have
17 weaknesses.

18 And I would say that when you
19 have ten or 15 prospective studies that
20 all point to the same thing, that that
21 is very, very strong data in the
22 direction of causation, although
23 technically the dogma would say you
24 cannot say that that shows causation.
25 To me, it's very strong data.

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1 BY MR. WONE:

2 **Q. And the studies cited in**
3 **paragraph 66 relate to vitamin D levels, not**
4 **supplementation, correct?**

5 A. That's correct, I don't believe
6 any of them were supplemented. I don't believe
7 any of them were supplemented.

8 **Q. So during the course of the**
9 **studies, none of the participants in the studies**
10 **cited in paragraph 66 took vitamin D as part of**
11 **the study?**

12 A. Not as part of the study, but
13 they may have been taking it on their own.
14 That's -- that's very possible. And that's why
15 it's a real-world situation.

16 **Q. Okay. If we could go on to**
17 **paragraph 67. It's on page 26.**

18 A. Okay.

19 **Q. And in this paragraph, you also**
20 **discuss prospective studies, correct?**

21 A. Yes.

22 **Q. And you used the phrase**
23 **"beneficial associations"?**

24 A. Yes.

25 **Q. And does that have -- does that**

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1 **phrase have the same meaning?**

2 A. Yes. Higher vitamin D
3 consumption was associated with better cognitive
4 function. And in this case, there are some
5 randomized clinical trials that are included in
6 this because they are a type of prospective study
7 in which you give a treatment to the person and
8 then see what the impact of that treatment is
9 rather than measuring their natural levels and
10 following them over time.

11 **Q. And is the study mentioned in**
12 **paragraph 67B one of the RCT studies you**
13 **mentioned?**

14 A. Did you say B or D?

15 **Q. B as in boy.**

16 A. B as in boy.

17 Yes. So study -- the study in
18 b, study b is a double-blind placebo-controlled
19 RCT.

20 **Q. Okay. I'd like to introduce**
21 **what's been marked as Exhibit MK12.**
22 **(Marked Exhibit MK12.)**

23 BY MR. WONE:

24 **Q. Do you see that exhibit, Doctor?**

25 A. I do. I'm going to open it

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1 right now.

2 Okay.

3 **Q. And is the study in Exhibit MK12**
4 **the study you were referring to in paragraph 67B**
5 **of your expert report?**

6 A. Yes.

7 **Q. And I'll refer to this as the**
8 **Grung study, if that's okay.**

9 A. As the what?

10 **Q. As the Grung study?**

11 A. The Grung study, yes. Yes.

12 **Q. Did the Grung study look at**
13 **vitamin D deficient adolescents?**

14 A. I don't believe that they were
15 deficient. I think they were Norwegian
16 adolescents broken into two groups who either
17 consumed vitamin D or not. This is a little bit
18 small on my screen, so I'm trying to...

19 **Q. There's a magnifying glass in**
20 **your viewer you can use to increase it.**

21 A. Okay. Here we go. Got it.
22 Thank you. Thank you so much. That really helps.

23 So there were 50 adolescents who
24 were assigned -- randomly assigned to either take
25 vitamin D or placebo and -- so that they were not

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1 recruited to be vitamin D deficient. They went --
2 when they measured the -- the vitamin D, it turned
3 out that the -- the average consumption was
4 deficient, but it doesn't look to me that they
5 intentionally recruited deficient participants.

6 **Q. But the participants were**
7 **deficient?**

8 A. Yes.

9 **Q. Vitamin D deficient?**

10 A. Yes. And that reflects the
11 population at large because in Scandinavia and in
12 the United States, there is a huge problem with
13 vitamin D deficiency. So it's not at all
14 surprising that when they recruited these healthy
15 kids, that many of them were deficient.

16 **Q. Are adolescents the target**
17 **audience for Prevagen?**

18 A. No, they're not.

19 **Q. And do adolescents typically**
20 **experience age-related cognitive decline?**

21 A. No, they don't.

22 **Q. How about mild cognitive**
23 **impairment?**

24 A. No, they don't. Again, this
25 paper was cited to give the view of the totality

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1 of the evidence showing that vitamin D seems to
2 have an impact on cognitive function and brain
3 function. I think that most of the papers that I
4 have referred to were in the target population.
5 There may be a few that were not. And I included
6 them just because it's more evidence to show that
7 vitamin D does have this effect. But most of the
8 papers that I -- that I -- the vast majority of
9 them are in the target population.

10 **Q. And could there be cognitive**
11 **function differences between adolescents and older**
12 **adults with age-related cognitive decline?**

13 MS. METZINGER: Objection to
14 form.

15 THE WITNESS: Can you rephrase
16 that, please?

17 BY MR. WONE:

18 **Q. Are there differences in the**
19 **cognitive function of adolescents versus older**
20 **adults with age-related cognitive decline?**

21 MS. METZINGER: Objection to
22 form.

23 THE WITNESS: I would suspect
24 so. I can't answer conclusively that
25 question, but I would suspect that

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1 that's the case, that there are
2 differences.

3 BY MR. WONE:

4 **Q. And is the reason why you can't**
5 **answer conclusively because cognitive function is**
6 **not your expertise?**

7 MS. METZINGER: Objection to
8 form and argumentative.

9 THE WITNESS: The reason I can't
10 answer is because I'm not familiar with
11 this particular question, which is the
12 difference in cognitive function
13 between adolescents and adults with
14 cognitive decline. There may be
15 experts in cognitive function who
16 aren't aware of that, and so it's --
17 it's -- I'm just not aware of that
18 particular question that you asked.

19 BY MR. WONE:

20 **Q. Okay. If you could go back to**
21 **paragraph 67 of your expert report, please.**

22 A. Yes.

23 **Q. Are there any other RCT studies**
24 **cited in paragraph 67 that would show that taking**
25 **vitamin D improves cognitive function?**

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1 A. Yes, I believe that there are.

2 **Q. And which ones? If you could**
3 **point me to the paragraph.**

4 A. 67c, this was an RCT of over
5 18 weeks of 82 healthy adults who were
6 supplemented with either 400 or 4,000
7 international units of vitamin D. They had two
8 doses, which is an extremely sophisticated way to
9 do a study if it's -- if -- if you have the
10 resources to do a dose-response study. So they
11 wanted to look at both of these two different
12 doses. And they found that -- that there were
13 improvements in cognitive function in the
14 high-dose group. And the improvements were
15 greater in people who had lower levels at
16 baseline.

17 So there was improvement in the
18 high-dose group as a whole, but the improvements
19 were better in those with -- who started out with
20 lower vitamin D. They did not see this effect on
21 nonverbal memory in the low-dose group.

22 **Q. And do you know the amount of**
23 **vitamin D in the high-dose group in the study that**
24 **you're referencing in paragraph C?**

25 A. 4,000 international units.

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1 **Q. And how much vitamin D is in**
2 **Prevagen?**

3 A. 2,000 international units.

4 **Q. So the dose -- the high-dose**
5 **used in that RCT in paragraph C was more than what**
6 **is contained in Prevagen, correct?**

7 A. Yes, that's correct.

8 **Q. Was there a placebo group in the**
9 **study that's -- that you're referring to in**
10 **paragraph C?**

11 A. There was not a placebo group.
12 There were -- there were two test groups. And so
13 the lower group took 400, the higher group took
14 4,000. So there was not a zero -- a zero group.

15 **Q. Okay. Are there any other**
16 **studies in paragraph 67 that you would say show**
17 **that vitamin D improves cognitive function?**

18 A. So in 67D, this is an RCT of 181
19 participants who have mild cognitive impairment,
20 and they were randomized to receive either 400 IUs
21 or placebo for 12 months and they -- these --
22 those researchers saw a significant improvement in
23 cognitive function in the vitamin D supplemented
24 group. And you'll note that this was published in
25 one of the best neurology journals that exists.

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1 **Q. And the participants in the**
2 **study that you're referring to in paragraph D,**
3 **they had mild cognitive impairment, correct?**

4 A. Yes, they did. Yes, they did.

5 **Q. And do you know what cognitive**
6 **function measure was used in that study?**

7 A. I'd have to look at the study.
8 I don't recall right now.

9 **Q. I'm marking what's introduced as**
10 **Exhibit MK13.**

11 **(Marked Exhibit MK13.)**

12 BY MR. WONE:

13 **Q. Do you see that, Doctor?**

14 A. Yes.

15 **Q. And is this the study that you**
16 **were referring to in paragraph 67D?**

17 A. Yes, it is.

18 **Q. And what cognitive function**
19 **measure was used in Exhibit MK13?**

20 MS. METZINGER: Mr. Wone, your
21 voice dropped a bit during that
22 question. Can you repeat it, please?

23 MR. WONE: Sure.

24 BY MR. WONE:

25 **Q. What cognitive function or --**

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1 **I'll start again.**

2 **How was cognitive function**
3 **measured in the study in MK13?**

4 A. It was -- the main outcome was
5 evaluated using the Chinese version of the
6 Wechsler Adult Intelligence Scale-Revised. And so
7 they had 11 tests that evaluated -- hang on a
8 second. Yeah, cognitive domains were evaluated
9 using 11 different tests involving vocabulary,
10 comprehension, arithmetic, digit span, et cetera.

11 **Q. And do you know whether the**
12 **Wechsler Adult Intelligence Scale-Revised tests**
13 **memory?**

14 A. I don't know. I don't know the
15 answer to that. They also used the Mini-Mental
16 State Examination, which is very, very frequently
17 used as a measure of general cognitive function.
18 Again, offhand, I don't recall if memory is a
19 focus of that.

20 But there's no question that
21 memory and cognitive function are very, very
22 intertwined. You know, memory is a part of
23 cognitive function. Memory affects cognitive
24 function. I'm not sure that you can actually
25 separate them very well.

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1 **Q. Did the study in Exhibit MK13**
2 **mention any results for the -- that second measure**
3 **you mentioned, the Mini-Mental State Examination?**

4 A. Hang on a sec.
5 I don't see it referred to.
6 Hang on a second. I don't see them referred to
7 those results.

8 **Q. Going back to paragraph 67 of**
9 **your expert report, are there any other studies**
10 **that you would say show that vitamin D intake**
11 **improves cognitive function?**

12 A. Yes, there's one more. I do
13 want to -- if I -- if I might make a comment on
14 the previous study.

15 **Q. Sure.**
16 A. As I -- as I said a few minutes
17 ago, that study was published in a very, very
18 high-quality clinical neurology psychiatry
19 journal. And assuming that the peer review is
20 excellent, which I think is a reasonable
21 assumption with a journal of that quality, then I
22 would assume that the methodologies that were used
23 were very likely to be appropriate for that
24 population. So I just wanted to point that out.

25 **Q. Okay.**

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1 A. The next one is E?

2 **Q. Yes.**

3 A. An RKTC performed in 55
4 overweight or obese women, 58 years, with low
5 vitamin D levels. They took either 600, 2000, or
6 4,000 IUs for one year and cognitive testing was
7 done at the end of the year.

8 **Q. So this study involved**
9 **overweight or obese women, correct?**

10 A. That's correct. That's correct.

11 **Q. And the -- and the women were --**
12 **had vitamin D deficiencies?**

13 A. You know, there's some argument
14 as to where 30 is a cut- -- is actually -- would
15 fall within the vitamin D deficient. It's
16 certainly on the low side. But some clinicians
17 would consider that deficient and some clinicians
18 would not.

19 And the other thing that I want
20 to point out about this trial and the other trial
21 that did not have a placebo, it's possible that
22 the researchers -- and I've been involved in
23 studies for which this was the case, or at least
24 I've been involved in discussions of studies where
25 this was the case. The researchers may have felt

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1 that it was unethical not to give everyone vitamin
2 D because it's such an important nutrient. So
3 many people are -- are deficient and it's such an
4 important nutrient for older women because of its
5 importance in bone health, particularly. So they
6 may have felt that they really needed to give --
7 that it was not ethical to have a zero group
8 because they would have had to tell woman who were
9 already taking vitamin D to stop taking it, and
10 that would probably be viewed as unethical and it
11 wouldn't get past the -- the Institutional Review
12 Board.

13 **Q. Okay. If we could turn to**
14 **paragraph 68.**

15 A. Yes.

16 **Q. You mentioned a case control**
17 **study --**

18 A. That's right.

19 **Q. -- that show beneficial**
20 **associations between higher vitamin D levels and**
21 **cognitive function. Do you see that?**

22 A. That -- that's right, yes.

23 **Q. And does the case control study**
24 **cited in paragraph 68 show that vitamin -- taking**
25 **vitamin D causes improvement in cognitive**

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1 **function?**

2 A. Again, this is a study that
3 shows association, so it is -- this -- and these
4 kinds of studies have fallen out of favor a little
5 bit because there are too many confounders with
6 these retrospective case control studies. And so
7 I threw this study in here just to add to the
8 data, but I would say that this is not one of the
9 stronger studies that -- that we've -- we're
10 discussing today. But they did show that using --
11 they used electronic medical records and they
12 showed that -- that people with dementia tended to
13 have lower levels of vitamin D.

14 **Q. Okay. And in paragraph 69, you**
15 **state that meta-analyses that show beneficial**
16 **association between higher vitamin D levels and**
17 **cognitive function. Do you --**

18 A. Mm-hmm.

19 **Q. -- see that?**

20 A. Yes.

21 **Q. And do any of the meta-analyses**
22 **cited in paragraph 69 show that taking vitamin D**
23 **causes improvement in memory?**

24 A. No. Let's see. A is
25 cross-sectional associations, B is cross-sectional

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1 and longitudinal. Then there's a systematic
2 review. Observational with three interventional
3 studies. So the interventional studies are the
4 ones that are generally considered to show
5 causation. The observational studies are generally
6 considered to show -- to show -- to show
7 association. And so the -- the -- whether the
8 meta-analyses can show or prove, as you say,
9 causation versus association depends on what kinds
10 of studies were included in the metaanalysis. And
11 it looks as the -- as though most of these were --
12 were observational studies, and so they have all
13 of the strengths and limitations of other
14 observational studies, only increased power to see
15 a different -- to see a change or an effect.

16 MR. WONE: Can we go off the
17 record for a moment?

18 THE VIDEOGRAPHER: We are going
19 off the record at 4:09 P.M.

20 (Off the record from 4:09 until
21 4:10.)

22 THE VIDEOGRAPHER: We are going
23 back on the record at 4:10 P.M.

24 BY MR. WONE:

25 Q. If you could turn to

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1 paragraph 78 of your report, Doctor, please.

2 A. Yes, I'm there.

3 Q. And in your -- in the first
4 sentence, you state that it's your expert opinion
5 that a supplement containing 500 to a thousand IUs
6 per day would be sufficient to achieve cognitive
7 benefits. Do you see that?

8 A. Yes, I do.

9 Q. And what cognitive benefits were
10 you referring to?

11 A. I'm referring to in this case
12 numerous cognitive benefits, including memory.

13 Q. Does any of the evidence in
14 Section 10 of your report show that vitamin D
15 causes improvement in any aspect of cognitive
16 function?

17 A. Can you say -- re- -- can you
18 rephrase that question, please?

19 Q. Does any of the evidence that
20 you cited in Section 10 of your report show that
21 vitamin D causes improvement in any aspect of
22 cognitive function?

23 MS. METZINGER: Objection to
24 form.

25 THE WITNESS: Yes, I believe

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1 that it does. There are some
2 randomized clinical trials that show
3 improvement. And then there is an
4 enormous amount of epidemiological data
5 showing very strong associations, and
6 that data should not be ignored. And
7 so I consider that data. And I know
8 that -- that, you know, there -- there
9 may be others who don't.

10 But I think that when you have
11 an enormous amount of epidemiological
12 data, it really points in the
13 direction, especially when it's -- when
14 they're very well-done prospective
15 studies, they certainly point in the
16 direction of causation. They don't
17 prove it, but they provide very, very
18 strong evidence.

19 And so I do believe that the
20 data that I have summarized shows that
21 vitamin D supplementation will help
22 with cognitive benefits, including
23 memory.

24 BY MR. WONE:

25 Q. And when you say "will help with

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1 cognitive benefits," do you mean that it causes
2 improvement in memory?

3 A. Yes. Yes. And -- and, again,
4 you know, as we -- as I said before, I -- I -- I
5 hope it's okay that I'm kind of repeating myself.
6 I think that this threshold of evidence is
7 intended to be different by regulators for dietary
8 supplements than for drugs. And if this were a
9 drug that was being evaluated, particularly a drug
10 that had potential very harmful side effects where
11 you have to be really careful with it, then the --
12 my threshold for evidence might be higher. For a
13 dietary supplement which has no adverse events
14 which is very likely to cause improvements for
15 people, in my opinion this evidence meets that
16 threshold.

17 Q. And what is the basis for your
18 belief that the standard for dietary supplements
19 is different?

20 A. Because in -- in the early
21 1990s, the Dietary Supplement Act was created in
22 order for dietary supplements to be regulated
23 differently than drugs and foods, and particularly
24 differently than drugs. And so -- and in the
25 guidance, as I said before, there are parts of the

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1 guidance that you can pull out that very clearly
2 intend there to be flexibility in interpreting
3 data, flexibility in applying data that they
4 are -- if they wanted these trials of dietary
5 supplements to be held to the same standards as
6 drugs, they would not have created separate
7 regulation for supplements.

8 **Q. Can a dietary supplement have a
9 harmful effect?**

10 MS. METZINGER: Objection to
11 form.

12 MR. de LEEUW: Do you mean --
13 I'm going to object as well. I mean,
14 maybe you want to put a little meat on
15 that question.

16 BY MR. WONE:

17 **Q. Do you understand my question,
18 Doctor?**

19 A. Yes. You asked if it's possible
20 that there could be dietary supplements that have
21 harmful effects. Yes, it is possible. And
22 even -- even with, as I said, the green tea trial,
23 the green tea catechin supplements are known to
24 have potentially harmful effects on the liver.
25 But in our study that we did, our clinical trial,

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1 we looked at that, and it was determined, and the
2 data and safety monitoring board agreed with it,
3 that the level of adverse events was so low that
4 it was nothing to be concerned about.

5 So in general, I think we think
6 of dietary supplements as supplements that are
7 very safe.

8 **Q. Would you go to paragraph 84 of
9 your report, Exhibit MK1, please.**

10 A. Yes.

11 **Q. In the second to last sentence,
12 you used the phrase "reasonable degree of
13 scientific certainty." What did you mean by that?**

14 A. Which -- which -- are we in 80?
15 In paragraph 80?

16 **Q. I'm sorry. Paragraph 84.**

17 A. Oh, I'm sorry. Paragraph 84.

18 **Q. Sorry, Doctor.**

19 A. Okay. On page 35 -- or 37. 35.

20 **Q. You used the phrase "reasonable
21 degree of scientific certainty" --**

22 A. Yes.

23 **Q. -- on the second to last line.**

24 A. Yes.

25 **Q. What did you mean by that?**

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1 A. What I mean by that is that I
2 don't think that we can ever be 100 percent
3 certain of anything in life, including science.
4 And so I am being honest here in saying that I am
5 not a hundred percent certain, but I think that I
6 have a reasonable degree of scientific certainty,
7 meaning I believe that there's enough evidence
8 that the statements are supported by competent and
9 reliable scientific evidence.

10 **Q. And when you say "statement,"
11 you're referring to -- are you referring to the
12 challenge claims?**

13 A. Yes.

14 **Q. Could you quantify what you mean
15 by what is a reasonable degree of evidence?**

16 A. I --

17 MS. METZINGER: Objection --

18 THE WITNESS: -- can't quant- --

19 MS. METZINGER: -- to form.

20 THE WITNESS: Go ahead.

21 MS. METZINGER: Objection.

22 Objection to the form.

23 Go ahead, Dr. Kurzer.

24 THE WITNESS: I can't -- I can't
25 quantify that. You know, this is

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1 basically saying that it's my judgment
2 as a scientist, as, you know, a leader
3 in my field, it is my judgment that the
4 evidence is supported, that the
5 evidence supports the claims. That's
6 what I'm saying. I can't quantify it.
7 I can just say that I with my judgment
8 and my background, my knowledge, my
9 experience, I can say that I believe
10 these statements to be valid.

11 MR. WONE: Okay. Could we go
12 off the record?

13 THE VIDEOGRAPHER: We are going
14 off the record at 4:18 P.M.

15 (Off the record from 4:18 until

16 4:40.)

17 THE VIDEOGRAPHER: We are going
18 back on the record at 4:40 P.M.

19 MR. WONE: Thank you for your
20 time this afternoon, Dr. Kurzer. We
21 don't have any further questions.

22 And I will turn it over to
23 co-counsel, Kate Matuschak.

24 THE WITNESS: Thank you,
25 Mr. Wone.

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EXAMINATION

BY MS. MATUSCHAK:

Q. Good afternoon, Dr. Kurzer.

A. Good afternoon, Ms. Matuschak.

Q. So as you know, my name is Kate Matuschak, and I am co-plaintiff with the Federal Trade Commission on behalf of the New York State Attorney General's Office, and I just wanted to ask you a few questions.**Could you please turn to paragraph 56 of your report, which is Exhibit 1. It's -- it's on numbered page 13, which is --**

A. Yes, I see.

Q. Great.

A. Mm-hmm.

Q. And in the first line of paragraph 56, you say "I believe that it is unlikely that intact AQ is absorbed and enters the brain."**Is "AQ" apoeaquorin in this context?**

A. Yes, it is.

Q. Okay. And why do you believe that it is unlikely that intact apoeaquorin is absorbed and enters the brain?

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A. Generally large molecules like apoeaquorin are not -- do not pass the blood brain barrier. I've subsequently learned that there are mechanisms through which apoeaquorin can combine with cholesterol and that there are examples of other large molecules that are able to get past the blood brain barrier this way, making them more lipophilic. So I might modify that and say that -- I mean, I still believe it's unlikely, but I think it's more plausible than I -- than I thought when I wrote the report.

Q. Okay. But you did not offer the opinion that you believe the mechanism by which apoeaquorin active -- by entering the brain, correct?

A. That's correct.

Q. And are you aware of the theory that apoeaquorin can exert effects on the brain because of its calcium binding properties?

A. Yes. I understand that those were the original -- I think that those were the original hypothesis about how apoeaquorin might exert its effects.

Q. And whose hypotheses were those?

A. I believe that they were the

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hypotheses of Moran and the authors of the earlier papers on apoeaquorin in -- in vitro and in vivo.

Q. Do you recall the authors of any of those earlier papers?

A. Right now, I don't.

Q. Okay.

A. I think -- you know, Moran I know for sure is one. And the others I don't recall right offhand. I'd have to look at my reference list.

Q. So for apoeaquorin to have this calcium binding effect, it would need to be in the brain intact. Would you agree with that?

MS. METZINGER: Objection to form.

THE WITNESS: I would say that that's -- it's possible that that's true. It's also possible it's not true because if there are segments of apoeaquorin that are released in di -- during digestion, they might -- the segments might be able to enter the brain and exert this effect. So there are other plausible mechanisms besides that the whole molecule of apoeaquorin

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enters the brain.

BY MS. MATUSCHAK:

Q. Right.**But the question is just about the calcium binding. So my question is, would intact -- the full protein intact need to be present to have a calcium binding effect?**

A. And what I'm saying is I don't know.

MS. METZINGER: Objection to form.

Go ahead.

THE WITNESS: Hmm?

MS. METZINGER: I just objected to the form. But you can go ahead, Dr. Kurzer.

THE WITNESS: I'm sorry.

MS. METZINGER: That's all right.

THE WITNESS: I'm falling into thinking this is just a conversation between friends.

What I'm trying to say is that it's possible that there are segments of apoeaquorin that are released during

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1 digestion that have calcium binding
2 properties and that perhaps they could
3 move into the brain and exert a calcium
4 binding effect.

5 BY MS. MATUSCHAK:

6 **Q. What --**

7 A. And I -- I -- I don't -- I'm
8 just -- I'm just hypothesizing something that
9 could be plausible.

10 **Q. And what's the basis for your
11 belief that that is plausible?**

12 A. The basis of my belief is basic
13 understanding of digestion and physiology of many
14 substances and the fact that we know that there
15 are metabolites of other substances that do go
16 into the brain even though the whole substance
17 cannot. And so it's not based on evidence. It's
18 not based on studies that have been done. It's
19 just a possibility.

20 **Q. Okay. So just to be clear,
21 you're not referring to any evidence that there is
22 some --**

23 A. That's --

24 **Q. -- derivative --**

25 A. -- right.

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1 **Q. -- of apoeaquorin that has a
2 calcium binding effect?**

3 A. That's right. That's right.

4 MS. METZINGER: Objection to the
5 form.

6 BY MS. MATUSCHAK:

7 **Q. And later on in this
8 paragraph 56 in your report, you discuss gut-brain
9 axis theory, correct?**

10 A. Yes, I do.

11 **Q. And if you could just turn to
12 page 14 where the paragraph spills over. In the
13 third --**

14 A. Yes.

15 **Q. -- line -- in the third line
16 down, you refer to peripheral intestinal
17 substances. What do you mean by that phrase?**

18 A. What I mean is by -- that there
19 are dozens and dozens and dozens of substances
20 that are synthesized in the gastrointestinal
21 tract, in the stomach and largely in the small
22 intestine, so some degree in the large intestine,
23 that exert an effect on the brain.

24 In fact, the gastrointestinal
25 tract is considered by some people to be the

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1 largest endocrine organ system in the body. And
2 this is fairly new knowledge. It's just the last
3 few decades that we've understood this, that --
4 that we have -- that there is a very clear
5 pathway - and there's no debate about this in the
6 nutritional science world in which I reside,
7 there's no controversy about this - substances,
8 hormones are secreted in the -- In the
9 gastrointestinal tract?

10 The best understood relate to
11 how we control food intake. How is food intake
12 controlled. How is it that we stop eating when
13 we've had -- we've eaten enough food. Well, one
14 thing is the stomach gets full and we feel a
15 little bit fuller. That's part of it. But in
16 addition, there are hormones that are secreted by
17 the -- by the cells of the stomach and the cells
18 lining the small intestine that -- that attach to
19 chemoreceptors on the vagus nerve which travels
20 from the intestine to the brain, and they actually
21 exert effects on the center in the brain which is
22 responsible for appetite.

23 So we -- we very quickly have a
24 regulatory system that tells us when we're -- when
25 we should be hungry because there hasn't been any

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1 food in a while or when we should be -- when we
2 should stop eating because we've eaten recently.
3 And it's these -- these chemical secreted in the
4 gastrointestinal tract that -- that signal the --
5 the nervous system through the vagus nerve which
6 then signals the -- the hypothalamus, the cells in
7 the appetite center. So this is well known.
8 We've known this a few decades.

9 But there are other substances
10 as well. Serotonin is secreted in the
11 gastrointestinal tract, and we know that serotonin
12 is a brain bioactive. And there are many, many
13 other examples of -- of neurotransmitters and
14 hormones that we know are active in the brain that
15 are actually secreted in the gastrointestinal
16 tract. So this is something that's very, very
17 well known, and I would say that we're getting
18 more and more and more and more data on this all
19 the time.

20 And the most recent --

21 **Q. Thank you. Thank you,
22 Dr. Kurzer.**

23 A. Okay.

24 **Q. I'm sorry. I just -- we're
25 running short on time, so I --**

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1 A. Sorry.
 2 **Q. -- just want to make sure I**
 3 **cover the -- the topics --**
 4 A. Okay.
 5 **Q. -- I want to cover.**
 6 A. I'm sorry.
 7 **Q. So I'm sorry to cut you off. I**
 8 **just would just ask if you could just answer the**
 9 **question. And -- and, you know, if your attorneys**
 10 **want to ask you questions if you want to add**
 11 **anything at the end, they can do that.**
 12 A. Okay.
 13 MR. de LEEUW: I object to that
 14 characterization. She was actually
 15 answering your question.
 16 MS. METZINGER: I agree with
 17 that and second that, Mr. de Leeuw.
 18 Thank you.
 19 BY MS. MATUSCHAK:
 20 **Q. So I would like you to look at**
 21 **paragraph 57 on this page 14 of your report.**
 22 A. Yes.
 23 **Q. And I just want to clarify. The**
 24 **references cited in this paragraph, number of them**
 25 **address apoeaquorin specifically, correct?**

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1 A. Right, yes.
 2 **Q. And none of them address**
 3 **products of apoeaquorin specifically --**
 4 A. That's correct.
 5 **Q. -- correct?**
 6 A. That's correct.
 7 **Q. No -- so no peptides derived**
 8 **from apoeaquorin are addressed in these**
 9 **references?**
 10 A. That's correct.
 11 **Q. And so none of them demonstrate**
 12 **any bioactive peptides resulting from apoeaquorin,**
 13 **correct?**
 14 A. That's correct.
 15 MS. METZINGER: Objection.
 16 Objection to form.
 17 BY MS. MATUSCHAK:
 18 **Q. I'd like you to turn now to**
 19 **paragraph 82 of your report. And that's page --**
 20 **it's numbered page 35, which I believe is page 37**
 21 **of this exhibit.**
 22 A. Is this the bibliography?
 23 **Q. Oh, I'm sorry. We may not be on**
 24 **the page.**
 25 MR. de LEEUW: What's the

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1 paragraph number? What's the paragraph
 2 number?
 3 MS. MATUSCHAK: Paragraph 82.
 4 THE WITNESS: I have it.
 5 MR. de LEEUW: Paragraph 82.
 6 It's on -- okay.
 7 THE WITNESS: I have that.
 8 MS. MATUSCHAK: Okay. Great.
 9 BY MS. MATUSCHAK:
 10 **Q. So in the fourth line of this**
 11 **paragraph, you say "substances in the GI tract can**
 12 **signal the brain through the vagal nerve and/or**
 13 **gut microbiota." And this is the theory you were**
 14 **just describing in your last answer, correct?**
 15 A. Yes.
 16 **Q. I'm sorry, not in your last**
 17 **answer but in your discussion of paragraph 56, the**
 18 **gut-brain axis, correct?**
 19 A. Yes.
 20 **Q. So are there -- does this mean**
 21 **there are two parts to your gut-brain axis theory,**
 22 **one involving vagal nerve and the other involving**
 23 **gut microbiota?**
 24 MS. METZINGER: Objection to
 25 form.

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1 THE WITNESS: This is exactly
 2 where I was going when I was talking a
 3 little bit too much a few minutes ago.
 4 BY MS. MATUSCHAK:
 5 **Q. Okay.**
 6 A. The more recent understanding of
 7 the gut-brain axis is that the microbiota are
 8 extremely active that the -- that there are --
 9 that there are compounds synthesized by the
 10 bacteria in the gut, including serotonin and a
 11 number of hormones are synthesized by the
 12 bacteria. So the bacteria are -- they secrete and
 13 synthesize very, very bioactive compounds. And
 14 this is very, very new, exciting work that's being
 15 funded at enormous levels at the -- by the federal
 16 government because we now know that the microbiome
 17 really has a huge impact on health.
 18 **Q. And you haven't cited any**
 19 **evidence that apoeaquorin can have an effect via**
 20 **the gut-brain axis theory, correct?**
 21 A. That's correct.
 22 MS. METZINGER: Objection to
 23 form.
 24 THE WITNESS: I haven't. And my
 25 understanding of the guidance is that a

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1 mechanism is not required. And that's
2 why, despite the fact, that I haven't
3 identified a mechanism for sure for
4 apoaquorin because there are plausible
5 mechanisms. My interpretation of the
6 FTC guidance is that the -- the -- this
7 is acceptable evidence, the fact that
8 there are plausible mechanisms.

9 BY MS. MATUSCHAK:

10 **Q. So in -- back to paragraph 82,**
11 **in the fifth line down, you say "products of AQ,"**
12 **apoaquorin, "digestion in the stomach and**
13 **intestine could be absorbed and exert effects on**
14 **the brain." This is your bioactive peptide**
15 **theory, correct?**

16 A. Yes.

17 **Q. But you don't -- as -- as I**
18 **think we've established, you don't -- you haven't**
19 **cited any evidence that apoaquorin actually**
20 **produces bioactive peptide, correct?**

21 A. That's correct.

22 MS. METZINGER: Objection to the
23 form.

24 BY MS. MATUSCHAK:

25 **Q. Okay. I'd like to go back now**

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1 **to paragraph 56 of your report. So paragraph 56**
2 **where you discuss the gut-brain axis theory, you**
3 **cite a biochemistry textbook, correct?**

4 A. Yes, I do.

5 **Q. And you believe that this is a**
6 **good reference to rely upon in general?**

7 A. In general, it's a -- it's a
8 good reference. It is an old reference and
9 probably outdated. And I know that I made a
10 mistake with that reference. And I think the
11 reason is because -- I actually wrote three or
12 four different reports that got merged into one
13 report, and I had to redo all of the references in
14 order to create one report. And it is very
15 possible that there was some kind of a mistake
16 made with the reference because of that. So I
17 apologize for that error.

18 **Q. No need to apologize. I just**
19 **want to make sure I understand, you know, the --**
20 **the basis for -- what you're citing as the basis**
21 **for the gut-brain axis theory.**

22 A. There are lots I could provide,
23 if you were interested, lots of other references.
24 So, really, I chose -- you know, in -- in many of
25 the points that I'm making, there are multiple

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1 references that could be cited. And in this case,
2 I certainly could provide other -- additional
3 references.

4 **Q. But here you cite just the**
5 **biochemistry book, correct?**

6 A. That's correct. But it's a
7 mistake. As I said, I think some references got
8 mixed up and that -- that is not the correct
9 reference for that comment.

10 **Q. But you would agree that this**
11 **reference doesn't support the statements in this**
12 **paragraph?**

13 A. Yes.

14 MS. METZINGER: Objection to
15 form.

16 BY MS. MATUSCHAK:

17 **Q. And were you familiar with**
18 **Dr. Berg, Dr. Jeremy Berg, before your work on**
19 **this case?**

20 A. No.

21 **Q. And in paragraph 57, I believe**
22 **you also cite Dr. Berg's book, and I'll just point**
23 **you to it. It's in the fifth line of that**
24 **paragraph.**

25 A. Same problem. This -- this

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1 reference got put in there and it shouldn't have
2 been. And I think it was the work -- it took me
3 many, many hours to redo all of the references
4 when the reports got merged, and so the wrong
5 reference was put here. So that reference that's
6 cited does not support that sentence. But as I
7 said, I could provide other references that would.
8 And, frankly, that 20 -- that 20-year-old textbook
9 is probably outdated, so I -- it would also be
10 interesting to look at a more current version of
11 it to see if they include these statements.

12 **Q. You don't cite any evidence of**
13 **amino acid small peptides containing, say, four**
14 **or more amino acid units that are -- that can be**
15 **absorbed in the small intestine, correct?**

16 MS. METZINGER: Objection to the
17 form.

18 THE WITNESS: I -- I may not
19 have a citation here, but there
20 certainly are some that I know of and
21 that I could easily provide references
22 for. For example, lunasin is a peptide
23 found in soy protein, which is 43
24 amino acids. And there have been
25 studies done because it's been shown to

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1 exert anticancer properties, so there's
 2 a lot of interest in it. There have
 3 been studies done where people have
 4 been given lunasin and it's measured in
 5 the blood. That shows --
 6 BY MS. MATUSCHAK:
 7 **Q. But you don't --**
 8 A. -- it's absorbed.
 9 **Q. But you don't refer to that in**
 10 **your report, correct?**
 11 A. I don't. I don't, no.
 12 **Q. Did you review the -- the report**
 13 **of Dr. Jeremy Berg that was submitted in this**
 14 **matter?**
 15 A. I did.
 16 **Q. Did you consider offering a**
 17 **rebuttal opinion to that report?**
 18 MS. METZINGER: Objection. I'm
 19 going to instruct the witness not to
 20 answer that question on the grounds of
 21 attorney-client privilege and work
 22 product.
 23 BY MS. MATUSCHAK:
 24 **Q. Are you going to follow that**
 25 **instruction?**

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1 A. I am.
 2 **Q. Would you consider yourself to**
 3 **be a biochemist?**
 4 A. I am a nutritional scientist,
 5 and biochemistry is a fundamental -- a
 6 fundamental -- it's a foundational discipline for
 7 nutritional science. Nutritional science is
 8 basically a combination of biochemistry and
 9 physiology as it applies to nutrition and to
 10 nutrients. How are they absorbed, how are they
 11 digested, what happens to them after, what about
 12 metabolism, these are things that I'm an expert
 13 in.
 14 And I have, as a nutritional
 15 scientist, I think a much broader understanding of
 16 nutrition and what happens to things that we
 17 consume than many biochemists who have -- tend to
 18 have very, very narrow approach, very narrow
 19 understanding of their particular field of
 20 expertise.
 21 So I am not trained in
 22 biochemistry at the Ph.D. level. I do not have a
 23 Ph.D. in biochemistry. I have taken many
 24 biochemistry classes. I have taught biochemistry
 25 classes. And I certainly consider myself to be an

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1 expert in nutritional biochemistry.
 2 **Q. And, yes, I appreciate that**
 3 **background, and I heard a lot of it earlier on**
 4 **today when we were talking about your background**
 5 **in general.**
 6 **The question is simply would you**
 7 **consider yourself to be a biochemist.**
 8 MS. METZINGER: Objection.
 9 Asked and answered.
 10 THE WITNESS: As I said, I
 11 consider myself to be a nutritional
 12 scientist. I have an expertise in
 13 nutritional biochemistry, yes. I know
 14 more nutritional biochemistry than most
 15 biochemists do.
 16 BY MS. MATUSCHAK:
 17 **Q. Other than reviewing literature,**
 18 **do you have any experience studying the mechanics**
 19 **of protein digestion?**
 20 MS. METZINGER: Objection to
 21 form.
 22 THE WITNESS: Can you explain
 23 what you mean by "experience"?
 24 BY MS. MATUSCHAK:
 25 **Q. Any -- any type of study of --**

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1 **of the mechanics of protein digestion.**
 2 A. I have not done studies on
 3 protein digestion. I have done studies on -- in
 4 fact, I was involved in studies that were done at
 5 UC Berkeley on the protein requirements of women.
 6 And, in fact, they're cited in the international
 7 guidelines for protein requirements. And so I've
 8 been involved in studies that looked at whole body
 9 protein utilization. I have not done studies on
 10 protein digestion per se myself.
 11 **Q. And other than reviewing**
 12 **literature, do you have any experience studying**
 13 **the mechanics of protein metabolism?**
 14 MS. METZINGER: Objection to
 15 form.
 16 THE WITNESS: I have not
 17 performed research on protein
 18 metabolism, but I have taught it to
 19 graduate students at the University of
 20 Minnesota. So I have enough of an
 21 understanding of the literature and the
 22 most current information that I can --
 23 that I can teach classes on that
 24 involve protein digestion and protein
 25 utilization. I have not done research

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1 on that myself.

2 BY MS. MATUSCHAK:

3 **Q. Can you tell me the general**
4 **subject matter of the classes that you taught that**
5 **involve protein metabolism or protein digestion?**

6 A. I teach an introductory
7 nutrition class which is an overview of all
8 nutrition, and we go through every nutrient
9 category in great detail. Two weeks ago I gave a
10 lecture to University of Minnesota students, to
11 150 students, on digestion and absorption. And
12 then as we talk about each category of
13 macronutrients when we -- when we talk about
14 protein, which we'll be doing I think next week,
15 then there will be lectures on pro- -- more
16 deeper, a deeper look at protein digestion,
17 absorption, metabolism.

18 **Q. Anything other than the lec- --**
19 **the intro -- introductory nutrition class and --**

20 A. I --

21 **Q. -- the lecture --**

22 A. Yeah, I've -- I've --

23 **Q. Sorry. Go ahead.**

24 A. I just didn't want to jump in
25 too quickly.

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1 I have taught a class a number
2 of times on protein and energy utilization where I
3 focus on the relationship between protein needs
4 and energy needs in humans, and so that's another
5 class that I've taught. And I've taught a class
6 on nutrition and endocrinology where I focus on --
7 and this is a high level class, this is for
8 doctoral students, focusing on the hormones that
9 influence nutrition and how nutrition influences
10 hormones. So I do consider myself an expert in
11 that subject.

12 **Q. Have you ever conducted a study**
13 **to determine whether a compound has entered the**
14 **bloodstream?**

15 MS. METZINGER: Objection to
16 form.

17 THE WITNESS: Yes, I have. In
18 the -- in the soy studies that I've
19 done with soy protein, we have been
20 very interested in bioactive compounds
21 in soy protein called isoflavones. And
22 I have done numerous studies in which
23 we have given -- we have given people
24 known amounts of isoflavones and then
25 measured them in the blood and in the

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1 urine to evaluate the, you know,
2 digestion and absorption.

3 BY MS. MATUSCHAK:

4 **Q. And what was your role in that**
5 **study?**

6 A. Principal investigator.

7 **Q. And do you have any other**
8 **studies that -- in which you have studied whether**
9 **a compound has entered the bloodstream?**

10 A. In the green tea trial that I
11 did which I also was a principal investigator of,
12 we -- those are both -- these are all NIH-funded
13 trials. We gave a capsule with a -- an extract of
14 green tea that contains catechins, which are the
15 bioactive compounds -- thought to be the bioactive
16 compounds in green tea, and we measured -- we --
17 we gave people a known amount of catechins, and we
18 measured them in the blood and in the urine. So
19 we know that they were absorbed and we know how
20 much they were excreted.

21 **Q. Have you ever conducted a study**
22 **involving a supplement that contains a protein?**

23 A. I've done lots of studies with
24 soy protein. So that is a protein. And in that
25 case, it is a protein that contains bioactive

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1 substances in it that are released when it's
2 consumed and when it's digested. The bioactive
3 substances are released.

4 **Q. Yes. But that is not a dietary**
5 **supplement containing a protein, is it?**

6 A. I don't know. I think you
7 should give me an example of a dietary supplement
8 containing a protein. Do you mean -- are you
9 speaking about apoaeguorin in particular that -- a
10 dietary supplement that is a protein? Is that
11 what you mean?

12 **Q. Right, right. Well, I mean, I**
13 **think you were speaking with Mr. Wone earlier**
14 **about the difference between, you know, dietary**
15 **supplements, studies involving dietary supplements**
16 **in which you could have, you know, some people**
17 **getting the placebo and other people getting the**
18 **active ingredient versus studies involving food**
19 **product where people know what they're getting.**
20 **And so I'm trying to draw a distinction between**
21 **those two in asking whether you've done any**
22 **studies in which the active ingredient in a**
23 **dietary supplement is a protein.**

24 MS. METZINGER: Objection to
25 form.

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1 THE WITNESS: No. Given the way
2 that you're phrasing this question, my
3 answer would be no. I have not -- you
4 know, I've given -- I've done studies
5 with supplements that were given as
6 pills. They were not proteins.
7 BY MS. MATUSCHAK:
8 **Q. Do you know how one might go**
9 **about testing apoaeguorin to determine what**
10 **products result from digestion?**
11 MR. de LEEUW: Object to form.
12 THE WITNESS: I think the best
13 way to do that would be to do a human
14 study in which you -- you -- you
15 provide apoaeguorin to people and then
16 you -- you remove fluid from the
17 stomach, from the small intestine, et
18 cetera, to see what is released.
19 There are other ways to do this.
20 You could use a radiolabeled
21 apoaeguorin where you have a -- you
22 know, it's called a -- you know, not --
23 not radioactive but a heavy -- an
24 isotope so that when apoaeguorin is
25 consumed, if it is absorbed, digested

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1 and parts of it are absorbed, you can
2 measure this isotope in the blood and
3 you can follow it to see where it goes.
4 So there are ways to do it.
5 They're difficult studies, but it's
6 possible to do those.
7 BY MS. MATUSCHAK:
8 **Q. Are you aware of such studies**
9 **being conducted by anyone?**
10 A. I am not aware that such studies
11 have been conducted. I'm also not aware that the
12 FTC guidance requires those kinds of studies. So,
13 you know, you're right, I don't think they've been
14 conducted. But despite that, I still stand behind
15 my conclusions.
16 **Q. Just to be clear, you're not**
17 **aware of any studies such as the ones you just**
18 **described being conducted with respect to**
19 **apoaeguorin, right?**
20 MR. de LEEUW: Objection.
21 THE WITNESS: Yes.
22 MR. de LEEUW: Object to --
23 MS. METZINGER: Objection.
24 MR. de LEEUW: -- the form of
25 the question.

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1 MS. METZINGER: Asked and
2 answered and to the form.
3 BY MS. MATUSCHAK:
4 **Q. Have -- are you familiar with**
5 **something called a PeptideCutter?**
6 A. A PeptideCutter? I'm not
7 familiar with that term. Yeah, I'm not familiar
8 with that term.
9 **Q. Okay. Are you familiar with an**
10 **Expasy tool? It's spelled E-X-P-A-S-Y.**
11 A. No, I'm not familiar with that.
12 **Q. Are you familiar with high**
13 **performance liquid chromatography or HPLC**
14 **analysis?**
15 A. Yes, I've used HPLC analysis and
16 I've used -- that's liquid chromatography. I've
17 also used GCMS, which is gas chromatography--mass
18 spectrometry. So they're -- they're methods of
19 analysis, and I have used them all.
20 **Q. Are those methods of analysis**
21 **expensive?**
22 A. Very.
23 MS. METZINGER: Objection to the
24 form.
25

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1 BY MS. MATUSCHAK:
2 **Q. How expensive effective would you**
3 **say an HPLC analysis is?**
4 A. You know, I really can't say
5 because it depends on what you're analyzing. The
6 machines are very expensive. So the machine that
7 you need to accomplish the analysis could be a few
8 hundred thousand dollars. Then when you're doing
9 the analysis of particular substances, you have to
10 get reagents and chemicals that could be quite
11 expensive in addition to the machine. It's also
12 fairly labor intensive, so you need staff who can
13 spend time.
14 So I can't really give you an
15 answer to how much it costs. It depends on the
16 particular substance that you're analyzing.
17 **Q. If the substance you were**
18 **analyzing is apoaeguorin, would that help you**
19 **estimate what the cost would be to conduct such an**
20 **analysis?**
21 A. Personally, I could speak with
22 colleagues and get advice from people about what
23 it would cost if you -- if you wanted to know that
24 information. There are some things that you need
25 to have in order to do this kind of analysis. You

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1 have to have a standard. So you have to have a --
2 a known amount of this substance which you can
3 use, and then they -- they could be quite
4 expensive to develop. I've known people who have
5 paid companies to create standards for them, and
6 that is a very large upfront cost.

7 So that's something that I would
8 have to look into. I wouldn't know that off the
9 top of my head.

10 **Q. Okay. Because I just -- sitting**
11 **here today, you -- you don't have enough**
12 **information to provide a cost estimate?**

13 A. That's correct.

14 **Q. And are you aware of anyone ever**
15 **conducting an HPLC analysis on apoaeguorin?**

16 A. You know, I'm not. I'd have to
17 look at the papers again to see if -- if the -- if
18 the published papers analyzed apoaeguorin. I
19 don't recall right now.

20 **Q. Okay. But just -- just sitting**
21 **here today, you're not aware of such an analysis**
22 **having been conducted?**

23 A. Yes.

24 MS. METZINGER: Objection.

25 Asked and answered.

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1 BY MS. MATUSCHAK:

2 **Q. And your opinion is that the**
3 **mechanism of action does not need to be known in**
4 **order for a dietary supplement to be effective,**
5 **correct?**

6 A. Yes. In order for it to be
7 effective and really in order -- yeah, in order
8 for it to make a claim of effectiveness, a
9 structure function claim.

10 **Q. And so the mechanism action**
11 **theories that you're advancing are possibilities**
12 **but not proven mechanisms, correct?**

13 A. That's correct.

14 MS. METZINGER: Objection to
15 form.

16 THE WITNESS: And -- and there
17 are -- there are lots of examples of
18 substances that are used even as drugs
19 for which we don't know the mechanism
20 of action.

21 You know, aspirin was -- has
22 been utilized since the late 1800s, and
23 it's only in the 1970s or '80s that the
24 mechanism of action was -- was used. I
25 remember when I was in graduate school

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1 learning about this, the teacher used
2 the word "miracle," that it was
3 considered a miracle drug. It did all
4 kinds of stuff but we didn't know why.
5 But doctors still recommended it.

6 And corticosteroids, cortisone,
7 is another one. Prednisone. For many
8 years, that was prescribed without
9 understanding the mechanism of action
10 at all. Now we understand what the
11 mechani- -- mechanism of action is of
12 that.

13 So there are lots of examples
14 even of drugs that are shown to be
15 effective and are therefore utilized
16 without knowing the mechanism of
17 action.

18 BY MS. MATUSCHAK:

19 **Q. Why did you think it was**
20 **important to opine on the mechanism of action in**
21 **this case?**

22 MS. METZINGER: Objection.

23 And I would caution Dr. Kurzer
24 that she not divulge any communications
25 with counsel in providing an answer to

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1 this question. If she's able to answer
2 the question without divulging such
3 information, she's free to do so.

4 THE WITNESS: I would choose not
5 to answer the question.

6 BY MS. MATUSCHAK:

7 **Q. Do you think that the mechanism**
8 **of action is relevant to an issue in this case?**

9 MS. METZINGER: Objection.

10 THE WITNESS: I'm sorry. Can
11 you repeat the question? I didn't
12 catch one part of it.

13 BY MS. MATUSCHAK:

14 **Q. Sure.**

15 **Do you think the mechanism of**
16 **action is relevant to an issue in this case?**

17 A. Is it relevant --

18 MS. METZINGER: Objection.

19 THE WITNESS: Is it relevant to
20 the primary issue in this case?

21 BY MS. MATUSCHAK:

22 **Q. To any issue in this case.**

23 MR. de LEEUW: Object to the
24 form. You're asking for a legal
25 opinion?

<p style="text-align: right;">309</p> <p>1 THE WITNESS: My --</p> <p>2 BY MS. MATUSCHAK:</p> <p>3 Q. Sorry.</p> <p>4 A. My interpretation of the</p> <p>5 guidance, the FTC guidance, is that a mechan- -- a</p> <p>6 mechanism of action is not necessary, therefore it</p> <p>7 is not relevant.</p> <p>8 MS. MATUSCHAK: Let's go off the</p> <p>9 record, please.</p> <p>10 THE VIDEOGRAPHER: We are going</p> <p>11 off the record at 5:17 P.M.</p> <p>12 (Off the record from 5:17 until</p> <p>13 5:26.)</p> <p>14 THE VIDEOGRAPHER: We're going</p> <p>15 back on the record at 5:26 P.M.</p> <p>16 MS. MATUSCHAK: Thank you for</p> <p>17 your time, Dr. Kurzer. I don't have</p> <p>18 further questions at this time.</p> <p>19 THE WITNESS: You're very</p> <p>20 welcome.</p> <p>21 MS. METZINGER: I do not have</p> <p>22 any questions for Dr. Kurzer.</p> <p>23 MR. de LEEUW: No questions.</p> <p>24 Thank you.</p> <p>25 THE VIDEOGRAPHER: This</p>	<p style="text-align: right;">311</p> <p>1 STATE OF TENNESSEE)</p> <p>2 COUNTY OF DAVIDSON) SS:</p> <p>3 I, Gary Schneider, TLCR No. 676, in and</p> <p>4 for the State of Tennessee, do hereby certify:</p> <p>5 That, prior to being examined, the</p> <p>6 witness named in the foregoing deposition was by</p> <p>7 me duly sworn to testify the truth, the whole</p> <p>8 truth and nothing but the truth;</p> <p>9 That said deposition was taken down by</p> <p>10 me stenographically at the time and place therein</p> <p>11 named, and thereafter transcribed via</p> <p>12 computer-aided transcription under my direction,</p> <p>13 and the same is a true, correct and complete</p> <p>14 transcript of said proceedings;</p> <p>15 Before completion of the deposition,</p> <p>16 review of the transcript was not requested. If</p> <p>17 requested, any changes made by the deponent (and</p> <p>18 provided to the reporter) during the period</p> <p>19 allowed are appended hereto.</p> <p>20 I further certify that I am not</p> <p>21 interested in the outcome of the action.</p> <p>22 Witness my hand this October 5, 2021.</p> <p>23</p> <p>24 s/Gary Schneider</p> <p>25 GARY SCHNEIDER, TLCR No. 676</p> <p>Certified Shorthand Reporter</p>
<p style="text-align: right;">310</p> <p>1 concludes the video deposition Mindy</p> <p>2 Kurzer. We are going off the record at</p> <p>3 5:26 P.M.</p> <p>4 (Deposition concluded at 5:26 P.M.)</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">312</p> <p>1 CERTIFICATE OF DEPONENT</p> <p>2</p> <p>3</p> <p>4 I hereby certify that I have read and examined</p> <p>5 the foregoing transcript, and the same is a true and</p> <p>6 accurate record of the testimony given by me.</p> <p>7</p> <p>8</p> <p>9 Any additions or corrections that I feel are</p> <p>10 necessary, I will attach on a separate sheet of paper to</p> <p>11 the original transcript.</p> <p>12</p> <p>13</p> <p>14 I hereby certify, under penalty of perjury, that</p> <p>15 I have affixed my signature hereto</p> <p>16 on the date so indicated.</p> <p>17</p> <p>18</p> <p>19 DATED:</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24 _____</p> <p>25 MINDY KURZER, Ph.D.</p>

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1 WITNESS: MINDY KURZER, Ph.D.
2 DATE: SEPTEMBER 29, 2021
3 CASE: FTC, et al., v. QUINCY BIOSCIENCE HOLDING, ET AL.
4 Please note any errors and the corrections thereof on
5 this errata sheet. The rules require a reason for any
6 change or correction. It may be general, such as "To
7 correct stenographic error," or "To clarify the record,"
8 or "To conform with the facts."
9 PAGE LINE CORRECTION REASON FOR CHANGE
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**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

FEDERAL TRADE COMMISSION and

THE PEOPLE OF THE STATE OF NEW
YORK, by LETITIA JAMES,
Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING
COMPANY, INC., a corporation;

QUINCY BIOSCIENCE, LLC, a limited
liability company;

PREVAGEN, INC., a corporation
d/b/a SUGAR RIVER SUPPLEMENTS;

QUINCY BIOSCIENCE
MANUFACTURING, LLC, a limited liability
company;

MARK UNDERWOOD, individually and as
an officer of QUINCY BIOSCIENCE
HOLDING COMPANY, INC., QUINCY
BIOSCIENCE, LLC, and PREVAGEN, INC.;
and

Defendants.

Case No. 1:17-cv-00124-LLS

**ERRATA SHEET FOR THE TRANSCRIPT
OF THE DEPOSITION OF MINDY KURZER, Ph.D.**

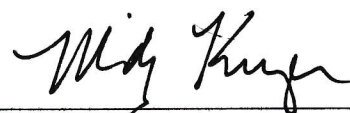
I, Mindy Kurzer, hereby make the following corrections to the transcript of my deposition, which occurred on September 29, 2021:

PAGE	LINE(S)	CORRECTION	REASON
14	16	Replace “1973” with “1974”	Incorrect
20	24	Replace “self-culture” with “cell-culture”	Transcription error
22	13	Replace “Loris Garby” with “Lars Garby”	Transcription error
34	19	Replace “and” with “of”	Transcription error
36	8	Replace “triable” with “tribal”	Transcription error
65	13	Replace “conscious” with “conscience”	Transcription error
102	19	Replace “canines” with “canine”	Transcription error
115	4	Replace “message” with “methods”	Transcription error
155	8	Replace “casing” with “casein”	Transcription error
180	6	Replace “ADL” with “LDL”	Transcription error
183	17	Replace “Jiam-Min” with “Jian-Min”	Transcription error
204	5	Replace “then” with “when”	Transcription error
246	4	Replace “enhanced” with “NHANES”	Transcription error
265	6	Replace “referred” to “refer”	Transcription error
266	3	Replace “RKTC” with “RCT”	Transcription error

283	8	Replace “?” with “.”	Incorrect.
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I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on October 29, 2021.



MINDY KURZER